Ongoing Clinical Trials Posters II

Thursday, February 18, 2016, 6:15 PM – 6:45 PM

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Presentation Number: CTP1

Publishing Title: Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

Author Block: Karen C. Johnston, Amy Fansler, Univ of Virginia, Charlottesville, VA

Abstract Body: Background: Hyperglycemia is common in acute stroke patients. Ischemic stroke patients with hyperglycemia have worse outcomes than those with euglycemia. There is clinical equipoise regarding management of hyperglycemia in acute ischemic stroke patients.
Objective: To assess the safety and efficacy of glucose control (80 - 130 mg/dL) using insulin infusion versus standard sliding scale insulin with target glucose >110 mg/dL or glucose of ≥ 150mg/dL for patients without diabetes at the time of enrollment. Study participants must be enrolled within 12 hours of stroke symptom onset and are expected to be enrolled within 3 hours of hospital arrival. Study participants will be recruited from approximately 60 sites including Neurological Emergencies Treatment Trials (NETT) sites and StrokeNet sites.
Sample Size: Expected to require 1400 subjects
Intervention: Study participants are randomized to intervention (IV insulin with target glucose 80-130 mg/dL) or control treatment (subcutaneous sliding scale insulin with target glucose 80-179 mg/dL). The intervention group uses the GlucoStabilizer® computerized decision support tool to guide therapy. Treatment continues for up to 72 hours.
Outcome Measures: The primary efficacy outcome is 90 day modified Rankin Scale with favorable outcome dependent on baseline stroke severity (sliding dichotomy). The primary safety outcome is severe hypoglycemia (<40 mg/dL).
Statistical Analysis: The efficacy analysis using a two sided alpha = 0.05, will have 80% power to demonstrate a clinically relevant treatment effect, defined as an absolute increase in favorable outcome of ≥7%. Safety will be declared if the absolute rate of severe hypoglycemia in the intervention group does not exceed that of the control group by more than 4%.
Trial Status: Enrollment is ongoing at nearly 60 sites. As of November 4, 2015, 700 subjects have been enrolled.
Sponsor: NIH-NINDS U01NS069498, U01NS056975, U01NS059041

Author Disclosure Block: K.C. Johnston: Research Grant; Significant; U01NS069498. **A. Fansler:** Research Grant; Significant; U01NS069498.

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Presentation Number: CTP2

Publishing Title: Randomized Evaluation of Low-dose tPA and Intensive Blood Pressure Lowering in Acute Ischemic Stroke: The ENCHANTED Trial

Author Block: Craig Anderson, The George Inst for Global Health, Sydney NSW, Australia; Pablo Lavados, Clinica Alemana-Univ del Desarrollo, Santiago, Chile; Vijay K Sharma, Natl Univ Hosp, Singapore, Singapore; Yining Huang, Peking Univ First Hosp, Beijing, China; Nguyen H Thang, 115 Hosp, Ho Chi Minh City, Viet Nam; Thompson Robinson, Univ of Leicester, Leicester, United Kingdom; Tsong-Hai Lee, Chang Gung Memorial Hosp, Taipei, Taiwan; Jong Sun Kim, Asan Medical Ctr, Seoul, Korea, Republic of; Richard Lindley, Hisatomi Arima, The George Inst for Global Health, Sydney NSW, Australia; Mark Parsons, Christopher Levi, John Hunter Hosp, Univ of Newcastle, Newcastle, Australia; Sheila O Martins, Hosp das Clinicas Porto Alegre, Porto Alegre, Brazil; The ENCHANTED Investigators

Abstract Body: Background: Controversy exists over the optimal dose (0.6 vs 0.9 mg/kg) of intravenous (iv)-tPA and associated level of blood pressure (BP) control in acute ischemic stroke (AIS). Studies indicate low-dose iv-tPA and more intensive BP control improves outcomes through lower risk of intracerebral hemorrhage.
Aims: ENCHANTED will assess in iv-rtPA-eligible AIS patients whether 0.6 mg/kg vs 0.9 mg/kg iv-rtPA and more intensive (systolic <140mmHg) vs guideline-recommended (systolic <185mmHg) provides non-inferior and superior efficacy, respectively, and lower risk of ICH.
Methods: An independent, quasi-factorial, active-comparative, prospective, randomized, open, blinded endpoint (PROBE), clinical trial using central internet randomization of AIS patients who fulfil local thrombolysis criteria. The study, which commenced in March 2012, completed recruitment of 3308 patients into the iv-tPA dose arm in August 2015 across a global network (100+ sites; 13 countries), to achieve the required sample size of 3300 (1650 per treatment arm) for >90% power to detect non-inferiority of low-dose iv-tPA. Patient 90-day follow-up was completed by end-2015; results will be announced in May 2016. The study is funded by the Australian government (NHMRC project grant 1020462).
Conclusions: Recruitment had completed into ENCHANTED dose arm, with results to be announced at the European Stroke Organisation conference in Barcelona, May 2016. Low-dose iv-tPA could provide more affordable, safer and effective thrombolytic treatment in AIS worldwide.

Author Disclosure Block: C. Anderson: Honoraria; Modest; Takeda China. Consultant/Advisory Board; Modest; Medtronic, Astra Zeneca. Research Grant; Significant; National Health and Medical Research Council (NHMRC) of Australia. **P. Lavados:** None. **V.K. Sharma:** None. **Y. Huang:** None. **N.H. Thang:** None. **T. Robinson:** None. **T. Lee:** None. **J. Kim:** None. **R. Lindley:** None. **H. Arima:** None. **M. Parsons:** None. **C. Levi:** None. **S.O. Martins:** None.

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Presentation Number: CTP3

Publishing Title: Tenecteplase versus Alteplase for Stroke Thrombolysis Evaluation Trial

Author Block: Jelle Demeestere, Mark Parsons, Andrew Bivard, John Hunter Hosp, Newcastle, Australia; Bruce Campbell, Royal Melbourne Hosp, Melbourne, Australia; Patrick McElduff, John Hunter Hosp, Newcastle, Australia; Chung Y. Hsu, 3. China Medical Univ Hosp and Graduate Inst of Clinical Medical Science, Taichung, Taiwan; Ken Butcher, Div of Neurology, Univ of Alberta, Edmonton, AB, Canada; Christopher Bladin, Florey Inst of Neuroscience and Mental Health, Melbourne, Australia; Richard Lindley, 6. Sydney Medical Sch-Westmead Hosp and The George Inst for Global Health, Sydney, Australia; Werner Hacke, Dept of Neurology, Heidelberg Univ Hosp, Heidelberg, Germany; Gregory Albers, Stanford Stroke Ctr, Stanford Univ Medical Ctr, Stanford, CA; Henry Ma, Phan Than, Dept of Med, Monash Univ, Melbourne, Australia; Carlos Molina, Dept of Neurology, Hosp Vall d'Hebron-Barcelona, Barcelona, Spain; Vincent Thijs, Stroke Dept, Austin Health, Melbourne, Australia; Geoffrey Donnan, Florey Inst of Neuroscience and Mental Health, Melbourne, Australia; Stephen Davis, Royal Melbourne Hosp, Melbourne, Australia; Christopher Levi, John Hunter Hosp, Newcastle, Australia

Abstract Body: Introduction:
In phase II studies, tenecteplase (TNK) has been shown to result in more complete reperfusion. We are conducting a phase III trial to compare TNK with Alteplase in acute ischemic stroke with onset < 4.5 hours in patients clinically eligible for intravenous alteplase who fulfil additional imaging criteria.
Design:
Multicentre, prospective, randomised, open-label, blinded endpoint (PROBE) phase III study. Patients are randomised 1:1 to standard dose intravenous alteplase (0.9 mg/kg) or TNK (0.25 mg/kg as a single bolus). There are two randomisation strata: first, randomisation is stratified by the presence or absence of internal carotid artery occlusion (ICAO) on baseline CT or MR angiography (capped at a maximum of 25% of the sample size); second, randomisation is stratified by size of infarct core (above or below 25 mL) on baseline CTP or diffusion-weighted MRI (DWI). We aim to include 1024 participants.

Population Studied:
Patients aged ≥ 18 years presenting with acute hemispheric ischemic stroke within 4.5 hours of stroke onset who are clinically eligible for IV alteplase. Multimodal CT or MRI including perfusion imaging must be performed before randomization. Infarct core and penumbral volumes will be calculated by automated software, RAPID or MIStar.
Primary Outcome:
Modified Rankin Scale (mRS) 0-1 at 3 months
Secondary Outcomes:
Reperfusion at 24 hours post stroke
Early clinical improvement (reduction in acute - 24 hour NIHSS score)
Modified Rankin Scale (mRS) 0-1 at 3 months (adjusted for baseline age and NIHSS)
Modified Rankin Scale 0-2 at 3 months
Categorical shift in mRS at 3 months

Infarct growth at 24 hours
Recanalization at 24 hours

Trial Status:

Since the trial commenced in August 2014, 39 patients have been recruited. Fifteen centres now open in Australia and a further 17 sites planned to open by 2016 across Taiwan, Canada and Europe. Interim analysis is planned after inclusion of the first 50 patients.

Author Disclosure Block: J. Demeestere: None. **M. Parsons:** None. **A. Bivard:** None. **B. Campbell:** None. **P. McElduff:** None. **C.Y. Hsu:** None. **K. Butcher:** None. **C. Bladin:** None. **R. Lindley:** None. **W. Hacke:** None. **G. Albers:** None. **H. Ma:** None. **P. Than:** None. **C. Molina:** None. **V. Thijs:** None. **G. Donnan:** None. **S. Davis:** None. **C. Levi:** None.

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Presentation Number: CTP4

Publishing Title: Carotid Revascularization Endarterectomy vs Stenting Trial (CREST): Presentation and Publication of Up To 10-year Results

Author Block: Alice J Sheffet, Rutgers, The State Univ of New Jersey-New Jersey Medical Sch, Newark, NJ; George Howard, Virginia Howard, Univ of Alabama at Birmingham, Birmingham, AL; Ariane Mackey, CHU de Quebec, Quebec City, Quebec, QC, Canada; William Brooks, Baptist Health Lexington, Lexington, KY; Michael D Hill, Univ of Calgary, Calgary, AB, Canada; Judith Lichtman, Yale Univ, New Haven, CT; Jenifer H Voeks, Medical Univ of South Carolina, Charleston, SC; Susan Hughes, MeeLee Tom, Linda Flaxman, Rutgers, The State Univ of New Jersey-New Jersey Medical Sch, Newark, NJ; Mary Longbottom, James Meschia, Thomas G Brott, for the CREST Investigators, Mayo Clinic Florida, Jacksonville, FL

Abstract Body: BACKGROUND: NINDS extended CREST follow up (F/U) to 10 years through 2016.
OBJECTIVE: To evaluate the long term clinical and anatomic durability of carotid stenting (CAS) vs surgery (CEA) defined by ipsilateral stroke and restenosis.
DESIGN: CREST (ClinicalTrials.gov NCT00004732) is a multicenter, randomized trial with blinded endpoint adjudication. F/U <10 years includes annual visits, ultrasounds and midpoint phone visits.
POPULATION: Of 2502 symptomatic and asymptomatic patients enrolled at 125 North American sites, 1921 were contacted to extend F/U from 4 to <10 years; 1695 (88%) consented.
OUTCOMES: The primary aim is to assess CAS vs CEA in the prevention of ipsilateral stroke. Secondary aims assess restenosis, effect modifiers of age, sex, stenosis and symptomatic status; temporal change in relative efficacy; and CREST patient outcomes compared to those in CMS data files.
ANALYSIS: Statistical analysis (time-to-event modeling with adjustment for major baseline covariates) will assess post procedural treatment differences from Day 31 up to 10 years, with 90% power to detect a 1.67 hazard ratio.
TRIAL STATUS: At 100 clinical sites, 1878 of 2502 survive. Of these, 296 graduated; 1051 are active; 71.7% of survivors from the initial cohort and 93.5% of those consented to long term F/U are retained; 209 finished 10 yr F/U; 1152 consented to CMS database linkage to compare patient outcomes to those in national databases.
Graduates receive certificates and pins. Subjects with final clinic visits and tests (2015-2016) receive $200. Sites get transportation funding and $150 for 10 yr visits with ultrasounds. Those with the best retention and compliance are honored at national meetings. Newsletters feature patient volunteers. Analyses are underway to describe national trends in CEA rates and outcomes in Medicare patients. CREST and European trial investigators are collaborating to merge data for meta-analysis. With F/U ending in July, the focus of 2016 will be on the analyses of primary and secondary outcomes of the long term F/U for publication and presentation.
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Author Disclosure Block: A.J. Sheffet: None. **G. Howard:** None. **V. Howard:** None. **A. Mackey:** None. **W. Brooks:** None. **M.D. Hill:** None. **J. Lichtman:** None. **J.H. Voeks:** None. **S. Hughes:** None. **M. Tom:** None. **L. Flaxman:** None. **M. Longbottom:** None. **J. Meschia:** None. **T.G. Brott, for the CREST Investigators:** None.

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Presentation Number: CTP5

Publishing Title: Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis: CREST-2 Update

Author Block: James F. Meschia, Mayo Clinic Jacksonville, Jacksonville, FL; Brajesh K Lal, Univ of Maryland Sch of Med, Baltimore, MD; George Howard, Univ of Alabama at Birmingham, Birmingham, AL; Gary S Roubin, Cardiovascular Associates of the Southeast, Birmingham, AL; Robert D Brown Jr., Mayo Clinic Rochester, Rochester, MN; Kevin M Barrett, Mayo Clinic Jacksonville, Jacksonville, FL; Seemant Chaturvedi, Univ of Miami, Miami, FL; Marc I Chimowitz, MUSC, Charleston, SC; Bart M Demaerschalk, Mayo Clinic Arizona, Phoenix, AZ; Virginia J Howard, Univ of Alabama at Birmingham, Birmingham, AL; John Huston III, Mayo Clinic Rochester, Rochester, MN; Ronald M Lazar, Columbia Univ Medical Ctr, New York, NY; Wesley S Moore, UCLA Medical Ctr, Los Angeles, CA; Claudia Scala Moy, NIH NINDS, Bethesda, MD; Tanya N Turan, Jenifer H Voeks, MUSC, Charleston, SC; Thomas G Brott, Mayo Clinic Jacksonville, Jacksonville, FL

Abstract Body: Over 100,000 carotid revascularization procedures are done annually in the US for asymptomatic carotid arterial stenosis. The safety of carotid endarterectomy (CEA) and carotid stenting (CAS), and the efficacy of medical therapy in altering the progression of atherosclerosis have improved. Therefore, the applicability of prior randomized trials in asymptomatic carotid stenosis to current treatment decisions has been called into question. The aim of the NINDS-funded CREST-2 is to compare CEA and intensive medical therapy (IMT) versus IMT alone (n=1240), and CAS and IMT versus IMT alone (n=1240), through two parallel randomized clinical trials at approximately 120 medical centers, including collaboration with NIH-StrokeNet. The composite primary outcome is any stroke or death within 44 days after randomization or ipsilateral ischemic stroke thereafter up to 4 years. Cognitive status is assessed on a regular schedule through computer-assisted telephone interview. IMT is directed centrally and includes tight control of blood pressure (systolic target < 140 mm Hg) and cholesterol (LDL target < 70 mg/dl) as well as lifestyle coaching.
As of October 21, 2015, 63 centers have been approved to randomize by the CREST-2 Site Selection Committee, and site selection is ongoing for up to 150 sites. 124 patients have been randomized. The Surgical and Interventional Management Committees have credentialed 239 surgeons and 81 interventionists. An additional 134 interventionists have been approved to submit additional cases via the CREST-2 Companion Registry which provides a CMS-reimbursed pathway for full credentialing in CREST-2. An update regarding the numbers of centers certified, surgeons and interventionists credentialed, and cases randomized will be provided.

Author Disclosure Block: J.F. Meschia: None. **B.K. Lal:** None. **G. Howard:** None. **G.S. Roubin:** None. **R.D. Brown:** None. **K.M. Barrett:** None. **S. Chaturvedi:** None. **M.I. Chimowitz:** None. **B.M. Demaerschalk:** None. **V.J. Howard:** None. **J. Huston:** None. **R.M. Lazar:** None. **W.S. Moore:** None. **C.S. Moy:** None. **T.N. Turan:** None. **J.H. Voeks:** None. **T.G. Brott:** None.

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Presentation Number: CTP6

Publishing Title: The FRONTIER Trial: Field Randomization of NA-1 Treatment in Early Responders

Author Block: Laurie Morrison, St. Michael's Hosp, Toronto, ON, Canada; **Richard H. Swartz**, Sunnybrook HSC, Toronto, ON, Canada; Michael D Hill, Univ of Calgary, Calgary, AB, Canada; Paul Raftis, Garrie Wright, Gary McAuley, Toronto Paramedic Services, Toronto, ON, Canada; Richard Verbeek, Sheldon Cheskes, Sunnybrook Ctr for Prehospital Med, Toronto, ON, Canada; Peter Dundas, Priya Kakar, Gordon Neville, Peel Regional Paramedic Services, Mississauga, ON, Canada; Jim Christenson, Univ of British Columbia, Vancouver, BC, Canada; Devin Harris, Stroke Services British Columbia, Vancouver, BC, Canada; Paul R Leslie, William Dick, British Columbia Emergency Health Services, Vancouver, BC, Canada; Daniel Selchen, St. Michael's Hosp, Toronto, ON, Canada; Leanne Casaubon, Toronto Western Hosp, Toronto, ON, Canada; Manu Mehdiratta, Yael Perez, Trillium Health Partners, Mississauga, ON, Canada; Oscar Benavente, Vancouver General Hosp, Vancouver, ON, Canada; Michael Tymianski, Univ of Toronto, Toronto, ON, Canada

Abstract Body: Background: Acute Ischemic Stroke is a rapidly progressive disorder, but all in-hospital neuroprotection trials initiated treatment ≥4 hrs from symptom onset. A prehospital approach as seen in FAST-MAG and STEMO studies makes earlier treatment possible. NA-1, a PSD-95 inhibitor, is a potent neuroprotectant shown to reduce stroke damage in primates and humans (ENACT).
Objective: To determine the safety and efficacy of treating stroke with NA-1 within 3 hours of symptom onset on clinical outcome after AIS.
Design: FRONTIER is a multicenter, randomized, double-blind placebo-controlled study of prehospital stroke treatment with NA-1 versus placebo.
Population Studied: 560 stroke patients, age 40-95, enrolled within 3 hours of symptom onset and who are ambulatory prior to event, with Los Angeles Motor Scale score 2-5 at time of randomization and without exclusions (seizure at onset, GCS < 10, severe hypertension, recent head trauma, pregnancy, major systemic illness, not independent at baseline, lack of IV access). Subjects are enrolled by study physicians and treated by paramedics en route to stroke centers. Treatment allocation is 1:1.
Intervention: IV NA-1 2.6 mg/kg or IV saline control infused over 10 minutes.
Outcomes: The primary outcome is the modified Rankin Scale (mRS) at 90 days using a sliding dichotomy approach according to basleine LAMS. Secondary outcomes include efficacy of NA-1 in reducing functional dependence, improving neurological outcome, increasing proportion of TIA's and improving activities of daily living.
Analysis: Recruitment is ongoing.
Trial status: Active, sites selected. Enrollment began March 2015 in the City of Toronto and Region of Peel, Ontario. Vancouver, B.C. began enrollment October 2015. 104 patients are enrolled as of the end of October 2015.

Author Disclosure Block: L. Morrison: None. **R.H. Swartz:** None. **M.D. Hill:** None. **P. Raftis:** None. **G. Wright:** None. **G. McAuley:** None. **R. Verbeek:** None. **S. Cheskes:** None. **P. Dundas:** None. **P. Kakar:** None. **G. Neville:** None. **J. Christenson:** None. **D. Harris:** None. **P.R. Leslie:** None. **W. Dick:** None. **D.**

Selchen: None. **L. Casaubon:** None. **M. Mehdiratta:** None. **Y. Perez:** None. **O. Benavente:** None. **M. Tymianski:** Ownership Interest; Significant; CEO of NoNO Inc..

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Presentation Number: CTP7

Publishing Title: The ENhanced Control of Hypertension ANd Thrombolysis strokE stuDy (ENCHANTED): Arm B - Randomized Evaluation of Intensive Blood Pressure Lowering in Acute Ischemic Stroke

Author Block: Craig Anderson, The George Inst for Global Health, Sydney NSW, Australia; Pablo Lavados, Clinica Alemana-Univ del Desarrollo, Santiago, Chile; Vijay K Sharma, Natl Univ Hosp, Singapore, Singapore; Yining Huang, Peking Univ First Hosp, Beijing, China; Nguyen H Thang, 115 Hosp, Ho Chi Minh City, Viet Nam; Thompson Robinson, Univ of Leicester, Leicester, United Kingdom; Tsong-Hai Lee, Chang Gung Memorial Hosp, Taipei, Taiwan; Jong Sun Kim, Asan Medical Ctr, Seoul, Korea, Republic of; Richard Lindley, Hisatomi Arima, The George Inst for Global Health, Sydney NSW, Australia; Mark Parsons, Christopher Levi, John Hunter Hosp, Univ of Newcastle, Newcastle, Australia; Sheila O Martins, Hosp das Clinicas Porto Alegre, Porto Alegre, Brazil; The ENCHANTED Investigators

Abstract Body: Background: Controversy exists over the level of blood pressure (BP) control in the hyperacute phase of acute ischemic stroke (AIS). Studies indicate that more intensive control of elevated BP improves outcomes by reducing intracerebral hemorrhage (ICH) after intravenous (iv)-tPA.
Aims: ENCHANTED will assess in iv-tPA-eligible patients whether intensive BP lowering (target systolic <140 mmHg) provides superior benefits and lower risk of any ICH compared to current BP guideline recommendations (systolic <180-185 mmHg).
Methods: An independent, quasi-factorial, active-comparative, prospective, randomized, open, blinded endpoint (PROBE), clinical trial evaluating both iv-tPA dose and BP control using central internet randomization of patients who fulfil local criteria for iv-tPA. Since the study commenced in March 2012, 1030 patients have been included in the BP arm across a global network (100+ sites; 13 countries), for a required sample of 2400 (1200 per arm) for >90% power to detect superiority of intensive BP lowering. The study is funded by the Australian government (NHMRC project grants) until 2018.
Conclusions: Early intensive BP lowering could provide more safer and more effective use of thrombolytic treatment in AIS worldwide.

Author Disclosure Block: **C. Anderson**, Takeda China, Modest,Honoraria; Medtronic, Astra Zeneca, Modest,Consultant/Advisory Board; National Health and Medical Research Council (NHMRC) of Australia, Significant,Research Grant; **P. Lavados**, None; **V.K. Sharma**, None; **Y. Huang**, None; **N.H. Thang**, None; **T. Robinson**, None; **T. Lee**, None; **J. Kim**, None; **R. Lindley**, None; **H. Arima**, None; **M. Parsons**, None; **C. Levi**, None; **S.O. Martins**, None.

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Presentation Number: CTP8

Publishing Title: Triple Antiplatelets for Reducing Dependency After Ischaemic Stroke (TARDIS). A Randomised Controlled Trial

Author Block: Jason Appleton, Margaret Adrian, Diane Havard, Joanne Keeling, James Kirby, Lisa Woodhouse, Jennifer Smithson, Michael Stringer, James Longmate, Katie Robson, Nikola Sprigg, **Philip M Bath**, Univ of Nottingham, Nottingham, United Kingdom

Abstract Body: Rationale: The risk of recurrence is greatest immediately after stroke or TIA. Existing prevention strategies (antithrombotic, lipid/blood pressure lowering, endarterectomy) reduce, not abolish, further events. Dual antiplatelet therapy - aspirin & clopidogrel (AC) for ischaemic heart disease, aspirin & dipyridamole (AD) for stroke - is superior to aspirin monotherapy. We hypothesise that intensive/triple antiplatelet therapy (ACD) is superior to guideline therapy (AD or C) in patients at high-risk of recurrence, providing bleeding does not become excessive.
Design: TARDIS is an international parallel-group prospective randomised open-label blinded-endpoint controlled trial assessing the safety and efficacy of intensive versus guideline antiplatelets given for 1 month in 4100 patients with acute ischaemic stroke or TIA. The primary outcome is ordinal stroke severity (fatal/severe non-fatal/mild/TIA/none) at 90 days. Secondary outcomes include death, myocardial infarction (MI), vascular events, function, bleeding, and serious adverse events.
Trial status: The trial commenced in April 2009 and will run for a total of 8.5 years. As of 8th October 2015, 2827 patients (stroke 1944, TIA 883) had been recruited from 106 centres in Denmark, Georgia, New Zealand and UK.
Funding: This project is funded by the National Institute for Health Research, Health and Technology Assessment Programme (10/104/24)
Disclaimer: The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Health and Technology Assessment Programme, NIHR, NHS or the Department of Health.

Author Disclosure Block: J. Appleton: None. **M. Adrian:** None. **D. Havard:** None. **J. Keeling:** None. **J. Kirby:** None. **L. Woodhouse:** None. **J. Smithson:** None. **M. Stringer:** None. **J. Longmate:** None. **K. Robson:** None. **N. Sprigg:** None. **P.M.W. Bath:** None.

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Presentation Number: CTP9

Publishing Title: NAVIGATE ESUS: Multicenter, Randomized, Double-blind, Phase III Trial of Rivaroxaban vs Aspirin for the Prevention of Recurrent Stroke and Systemic Embolism in Patients with Recent Embolic Stroke of Undetermined Source

Author Block: Scott E Kasner, Univ of Pennsylvania, Philadephia, PA; Angel Chamorro, Univ of Barcelona, Barcelona, Spain; Michal Bar, Univ of Ostrava, Ostrava, Czech Republic; Joan Marti-Fabregas, Hosp de la Santa Creu i Sant Pau, Barcelona, Spain; Gustavo Santo, Univ of Coimbra, Coimbra, Portugal; Meritxell Gomis, Hosp Univri Germans Trias i Pujol, Badalona, Spain; Helmi Lutsep, Oregon Health and Science Univ, Portland, OR; Mukul Sharma, McMaster Univ / Population Health Res Inst, Hamilton, ON, Canada; Peter Dioszeghy, Josa Andras Hosp, Nyiregyhaza, Hungary; Calin Pater, Bayer Healthcare, Leverkusen, Germany; Hardi Mundl, Bayer Healthcare, Wuppertal, Germany; Scott D Berkowitz, Bayer Healthcare, Whippany, NJ; Ashkan Shoamanesh, Stuart J Connolly, McMaster Univ / Population Health Res Inst, Hamilton, ON, Canada

Abstract Body: Background: Embolic stroke of undetermined source (ESUS) is a non-lacunar stroke without significant proximal arterial stenosis or an identified high-risk source of cardioembolism. The risk of recurrent stroke in ESUS patients is substantial despite current standards of care, which include aspirin (ASA). Anticoagulation with a factor Xa inhibitor could optimize secondary stroke prevention in this patient population.
Objective: To determine whether rivaroxaban is superior to ASA for reducing the risk of recurrent stroke and systemic embolism after recent ESUS.
Design: NAVIGATE ESUS (NCT02313909) is a multicenter, international, double-blind, active-controlled, randomized clinical trial.
Population: Seven thousand participants aged ≥50 years with recent (50%, history/evidence of atrial fibrillation after at least 24 hours of cardiac monitoring, intracardiac thrombus on echocardiography, or other identified stroke etiology. Patients with specific contraindications to aspirin or rivaroxaban, established indications for chronic anticoagulation or antiplatelet therapy, and/or GFR<30mL/min/1.73/m2 are ineligible.
Intervention: Rivaroxaban 15 mg daily or ASA 100 mg daily (1:1 blinded randomization).
Primary Outcome: Time to recurrent stroke or systemic embolism. The primary safety outcome is major bleeding (ISTH criteria).
Analysis: The primary efficacy intention-to-treat analysis will compare rivaroxaban to ASA using an age-stratified log-rank test. With 450 primary events anticipated, the study will have 90% power to detect a 30% reduction in the primary outcome by rivaroxaban vs. ASA.
Trial Status: Recruitment began in December of 2014 and will continue at approximately 480 sites in 31 countries.
Contact information: Robert G. Hart (Co-Principal Investigator with Stuart J. Connolly), McMaster University and Population Health Research Institute, Robert.Hart@phri.ca, Tel: 905 521 2100 ex 40367, Fax: 905 577 1427

Trial Email: NavigateEsus@phri.ca
Trial Sponsor: Bayer Healthcare

Author Disclosure Block: S.E. Kasner: None. **A. Chamorro:** None. **M. Bar:** None. **J. Marti-Fabregas:** None. **G. Santo:** None. **M. Gomis:** None. **H. Lutsep:** None. **M. Sharma:** None. **P. Dioszeghy:** None. **C. Pater:** None. **H. Mundl:** None. **S.D. Berkowitz:** None. **A. Shoamanesh:** None. **S.J. Connolly:** None.

Presentation Number: CTP10

Publishing Title: TEMPO-2: Tenecteplase For Minor Ischemic Stroke With Proven Acute Symptomatic Occlusion Trial-2

Author Block: Shelagh B Coutts, Carol Kenney, Amy Ying Xin Yu, Univ of Calgary, Calgary, AB, Canada; Mark Parsons, John Hunter Hosp, Newcastle, Australia; Peter J Kelly, Neurovascular Unit for Neurovascular Unit for Translational and Therapeutics Res, Dublin, Ireland; Michael D Hill, Univ of Calgary, Calgary, AB, Canada

Abstract Body: Background:
Minor stroke and TIA with an intracranial occlusion are associated with a 20-30% risk of deterioration and disability. Tenecteplase (TNK-tPA) compared to alteplase is easier to administer, has a longer half-life, higher fibrin specificity and possibly less intracerebral hemorrhage (ICH). It may be an ideal thrombolytic agent in this population. A pilot study, TEMPO-1, showed feasibility and safety. TEMPO-2 (NCT02398656) examines tenecteplase for the treatment of minor stroke with imaging defined intracranial occlusion.
Methods:
Multi-center, prospective, open-label, randomized controlled trial comparing tenecteplase to best standard of care. Patients with an NIHSS < 6, intracranial arterial occlusion on CTA, and within a 12h treatment window will be enrolled (expected sample size of 1274 patients). Patients will be randomized 1:1 using a randomized minimization method to receive 0.25mg/kg intravenous tenecteplase or control, defined as the best standard of care and minimally must include immediate treatment with ASA. The primary outcome will be a responder analysis defined by the modified Rankin Scale score at 90 days. Safety will be assessed by the rate of symptomatic ICH. Secondary outcomes include complete neurological (NIHSS 0-1) and functional (mRS 0-1) recovery at 90 days, recanalization at 4-8h on CTA and minor bleeding.
Trial status:
The study has received regulatory approval and is registered. The first 15 patients have been enrolled. This study is in the site activation phase and is expected to continue for up to 5 years.

Author Disclosure Block: **S.B. Coutts:** Research Grant; Significant; TEMPO-2 is funded by Alberta Innovates Health Solutions and the Calgary Stroke Program. **C. Kenney:** None. **A. Yu:** None. **M. Parsons:** None. **P.J. Kelly:** None. **M.D. Hill:** Research Grant; Significant; TEMPO-2 is funded by Alberta Innovates Health Solutions and the Calgary Stroke Program. Other; Significant; Hoffmann-La Roche Canada Ltd provided study drug for TEMPO-1 through a grant agreement with the University of Calgary.

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Presentation Number: CTP11

Publishing Title: DEFUSE 3

Author Block: Gregory W Albers, Maarten Lansberg, Stephanie Kemp, Soren Christensen, Jenny Tsai, Michael Mlynash, Sun Kim, Greg Zaharchuck, Stanford Stroke Ctr, Palo Alto, CA; Sharon Yeatts, Medical Univ of South Carolina, Charleston, SC; Max Wintermark, Roland Bammer, Stanford Stroke Ctr, Palo Alto, CA; Yuko Palesch, Medical Univ of South Carolina, Charleston, SC; Phil Lavori, Stanford Dept of Biomedical Data Science, Palo Alto, CA; Joseph P Broderick, Univ of Cinncinati, Cinncinati, OH; Michael Marks, Stanford Stroke Ctr, Palo Alto, CA; on behalf of the DEFUSE 3 Investigators

Abstract Body: DEFUSE 3 is a prospective randomized Phase III multicenter controlled trial of patients with acute ischemic anterior circulation strokes due to large artery occlusion treated between 6-16 hours of stroke onset with endovascular thrombectomy therapy vs. control. The primary endpoint, the modified Rankin Score, will be assessed at 3 months. The purpose of DEFUSE 3 is to assess the safety and efficacy of thrombectomy in carefully selected patients in an extended time window.
Patients who meet the inclusion criteria will undergo either CT Perfusion/CTA or MR DWI/Perfusion/MRA studies prior to randomization. Patients who have evidence of an ICA or MCA M1 occlusion and a Target Mismatch Profile based on locally installed RAPID software will be randomized in a 1:1 ratio to treatment with one or more DEFUSE 3 approved thrombectomy devices (Only 510K approved thrombectomy devices will be used) plus standard medical therapy versus standard medical therapy alone.
Randomization of a maximum of 476 patients is planned. At the first interim analysis when 200 subjects complete the follow-up, if the overall analysis crosses the futility boundary, a novel adaptive design will identify, if it exists, a subgroup with the best prospect for showing benefit from endovascular treatment, based on baseline ischemic core lesion volumes and the time to treatment. The second Interim analyses will be conducted at 340 patients at which time the study may stop for efficacy/futility, or the inclusion criteria may be adjusted in the case of futility.
DEFUSE 3 is funded by the NINDS and will be administered though the NIH StrokeNet. The clinical coordinating center is the Stanford Stroke Center, the national coordinating center is the University of Cincinnati and the data management center is the Medical University of South Carolina. Up to 45 sites (35 NIH StrokeNet sites and 10 non-StrokeNet sites) will participate.

Author Disclosure Block: G.W. Albers: Research Grant; Significant; NIH. Honoraria; Significant; Medtronic, iSchemaView. Ownership Interest; Significant; iSchemaView. **M. Lansberg:** None. **S. Kemp:** None. **S. Christensen:** Consultant/Advisory Board; Significant; iSchemaView. **J. Tsai:** None. **M. Mlynash:** None. **S. Kim:** None. **G. Zaharchuck:** None. **S. Yeatts:** None. **M. Wintermark:** None. **R. Bammer:** None. **Y. Palesch:** Consultant/Advisory Board; Modest; Brainsgate. **P. Lavori:** None. **J.P. Broderick:** None. **M. Marks:** None.

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Presentation Number: CTP12

Publishing Title: Thrombolysis for Acute Wake-up and Unclear-onset Strokes With Alteplase at 0.6mg/kg (THAWS) Trial: An Update

Author Block: Masatoshi Koga, Kazunori Toyoda, Natl Cerebral and Cardiovascular Ctr, Suita Osaka, Japan; Kazumi Kimura, Nippon Medical Sch, Tokyo, Japan; Haruko Yamamoto, Natl Cerebral and Cardiovascular Ctr, Suita Osaka, Japan; Makoto Sasaki, Iwate Medical Univ, Morioka, Japan; Hamasaki Toshimitsu, Natl Cerebral and Cardiovascular Ctr, Suita Osaka, Japan; Takanari Kitazono, Kyushu Univ, Fukuoka, Japan; Junya Aoki, Nippon Medical Sch, Tokyo, Japan; Kenta Seki, Toshihiro Ide, Sohei Yoshimura, Kazuo Minematsu, Natl Cerebral and Cardiovascular Ctr, Suita Osaka, Japan

Abstract Body: Purpose: About one fourth of acute ischemic stroke patients suffer with unclear-onset time, e.g., during sleep. A large group of these patients have a potential to recover with intravenous thrombolysis. MRI findings with positive DWI and negative FLAIR (negative FLAIR pattern) can identify ischemic stroke patients within 4.5 h from symptom onset.
Aim and hypothesis: We aim to test the efficacy and safety of intravenous thrombolysis with alteplase at 0.6mg/kg (officially approved dosage in Japan) in ischemic stroke patients with unclear-onset time and a negative FLAIR pattern. We hypothesize that stroke patients with unclear-onset time and a negative FLAIR pattern will improve with intravenous thrombolysis more frequently than those without.
Design: The THAWS (ClinicalTrials.gov identifier: NCT02002325) is an investigator initiated, multicenter (39 hospitals in Japan), prospective, randomized, open label, blinded-endpoint assessment clinical trial. Trial protocol was published in International Journal of Stroke (2014;9:1117-1124). Three hundred patients with a negative FLAIR pattern will be randomized 1:1 to either intravenous thrombolysis with alteplase (n=150) or standard treatment (n=150) within 4.5 h after symptom recognition. Although we initially enrolled patients with a baseline NIHSS between 5 and 25, recently we revised our protocol to add those with the NIHSS between 2 and 4. We generally follow the trial design of the WAKE-UP (ClinicalTrials.gov Identifier: NCT01525290). Intracranial hemorrhage will be assessed on follow-up MRI after 22-36 h. Primary outcome will be assessed at 90 days.
Study outcomes: The primary efficacy endpoint is favorable outcome defined by 90-day mRS 0-1. The safety outcome measures are 24-h symptomatic intracranial hemorrhage, serious bleeding during study period and 90-day mortality.
Update: Patient enrollment was started in May 2014. Initial safety assessment was approved from the Ministry of Health, Labour and Welfare in Oct 2014. Until Oct 2015, 22 patients were enrolled.
Discussion: This trial may help determine whether low-dose alteplase should be recommended for ischemic stroke patients with unclear-onset time using MRI-based selection.

Author Disclosure Block: **M. Koga:** Honoraria; Modest; Mitsubishi Tanabe Pharma Corporation, Kyowa Hakko Kirin Co., Ltd. **K. Toyoda:** Other Research Support; Modest; Mitsubishi Tanabe Pharma Corporation. Honoraria; Modest; Mitsubishi Tanabe Pharma Corporation. **K. Kimura:** None. **H. Yamamoto:** None. **M. Sasaki:** None. **H. Toshimitsu:** None. **T. Kitazono:** Other Research Support; Significant; Mitsubishi Tanabe Pharma Corporation. Honoraria; Significant; Mitsubishi Tanabe Pharma

Corporation. **J. Aoki:** None. **K. Seki:** None. **T. Ide:** None. **S. Yoshimura:** None. **K. Minematsu:** Honoraria; Modest; Mitsubishi Tanabe Pharma Corporation, Kyowa Hakko Kirin Co., Ltd., Nippon Boehringer Ingelheim Co., Ltd., Medical Hirata Inc., Stryker Japan K.K..

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Presentation Number: CTP13

Publishing Title: The ECASS-4: ExTEND Study

Author Block: Peter A Ringleb, Univ Hosp, Heidelberg, Germany; ECASS-4 Steering Committee

Abstract Body: ***Hypothesis***
Thrombolytic therapy with rtPA is effective within a 4.5 hour time-window based on plain CT-imaging. We hypothesized that ischemic stroke patients selected with significant penumbral DWI-PWI mismatch MRI at 4.5 - 9 hours after onset of stroke will have improved clinical outcomes when given i.v. rtPA as compared to placebo.
Study Design
ECASS-4:ExTEND is an investigator driven, phase III, randomized, multi-center, double-blind, placebo-controlled study. Ischemic stroke patients presenting within 4.5 and 9 h of stroke onset (or waking up with stroke symptoms) with NIHSSS of 4 to 26 and fulfilling predefined MRI-criteria (infarct core volume (DWI) <100ml, perfusion lesion: infarct core mismatch ratio >1.2 and perfusion lesion minimum volume of 20ml) can be randomized.
Study Outcome
The primary outcome measure will be the categorical shift in the mRS at day 90. Estimated sample size is 264 patients. Clinical secondary outcomes will be disability at day 90 dichotomized as favorable outcome (mRS 0-2) at day 90. Safety endpoint will include symptomatic intracranial hemorrhage and death.
Study Status
Randomization started in Feb 2014. In the meanwhile 26 centers in 7 European countries have been initiated. Until Sep 30th 65 patients (mean age 74.8 yrs, mean NIHSS 10.9) have been randomized. Combined Analysis with the Australian ExTEND study is preplanned.

Author Disclosure Block: P.A. Ringleb: None.

Presentation Number: CTP15

Publishing Title: Head Position in Stroke Trial (HeadPoST): an International Cluster Randomized Trial

Author Block: Pablo M Lavados, Paula Muñoz-Venturelli, Verónica V Olavarría, Alejandro M Brunser, Clínica Alemana de Santiago, Univ del Desarrollo, Santiago, Chile; Octavio Pontes, Hosp das Clínicas da Faculdade de Medicina de Ribeirão Preto, Univ of Sao Paulo, Sao Paulo, Brazil; Hisatomi Arima, The George Inst for Global Health, Sydney NSW, Australia; Maree Hackett, The George Inst for Global Health, Sydnew NSW, Australia; Joyce Lim, The George Inst for Global Health, Sydney NSW, Australia; Sandy Middleton, Nursing Res Inst, Australian Catholic Univ & St Vincent's Health, Sydney NSW, Australia; Caroline Watkins, Univ of Central Lancashire, Preston, United Kingdom; Thompson Robinson, The George Inst for Global Health, University of Leicester, United Kingdom; Bin Peng, Liying Cui, Peking Union Medical Coll Hosp, Chinese Academic Medical Science, Beijing, China; Tsong Hai Lee, Linkou Chang Gung Memorial Hosp, Taoyuan, Taiwan; Ruey-Tay Lin, Kaohsiung Medical Univ Chung-Ho Memorial Hosp, Kaohsiung, Taiwan; **Craig Anderson**, The George Inst for Global Health, Sydney NSW, Australia; The HeadPoST Investigators

Abstract Body: Background: Limited evidence exists over the optimal head position in patients with either acute ischemic stroke (AIS) or intracerebral hemorrhage (ICH). Potential benefits of lying flat in AIS (increased collateral blood flow) and sitting up in ICH (reduced cerebral edema) may be offset by increased risks of aspiration pneumonia and cardiac-respiratory failure.
Aims: To compare the effects of lying flat (0°) with sitting up (≥30°) head position in the first 24 hours of admission for patients with acute stroke on poor outcome (death or disability) at 90 days.
Methods: A multicenter, prospective, cluster randomized, crossover, blinded outcome assessed, clinical trial in 100+ hospitals in Australia, Brazil, Chile, China, India, Sri Lanka, Taiwan, and the United Kingdom. Key aspects of the study to avoid bias include consecutive recruitment (selection bias), thorough preparation and training of site staff (compliance and overcome local barriers) and central blinded outcome assessment (observer bias). Sample size is calculated on each hospital recruiting 140 consecutive patients. Funding is from the National Health and Medical Research Council (NHMRC) of Australia.
Results: Site set-up in the study is ongoing with 60 of 100+ hospitals actively recruiting 3000+ patients to date. Adherence to the randomized head position and follow-up is excellent. The study is ongoing through 2016.
Conclusions: Cooperation, training and communications are essential for set up and conduct of this complex intervention (service remodelling) study. Given uncertainty over benefits:risks, reliable randomized evidence is required to standardize clinical and nursing practice.

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Presentation Number: CTP16

Publishing Title: TICH-2 Trial - Tranexamic Acid for Intracerebral Haemorrhage 2

Author Block: Philip M Bath, Jason Appleton, Hayley Foster, Margaret Adrian, Michael Stringer, James Longmate, Joanne Keeling, James Kirby, Jennifer Smithson, Polly Scutt, Katie Robson, **Nikola Sprigg**, Univ of Nottingham, Nottingham, United Kingdom

Abstract Body: Rationale: To assess in a pragmatic phase III prospective double blind randomised placebo-controlled trial whether tranexamic acid is safe and reduces death or dependency after spontaneous intracerebral haemorrhage (ICH). The results will determine whether tranexamic acid should be used to treat ICH.
Design: Patients will be randomised (1:1) to receive either tranexamic acid or placebo (0.9 % saline) within 8 hours of acute primary intracerebral haemorrhagic stroke.
Randomisation will be computerised and minimised on key prognostics age; sex; time since onset; systolic blood pressure; stroke severity (NIHSS); presence of intraventricular haemorrhage and known history of antiplatelet treatment. Patients, investigators and outcome assessors will be blind to treatment allocation. The primary outcome is death or dependency (modified Rankin Scale, mRS) and telephone follow-up is at day 90.
Trial status: The start-up phase of the trial commenced on 1st March 2013, the main phase commenced 1st April 2014. The recruitment target was 300 participants in the start-up phase and 2,000 in the main phase. As of 21st October, 2015 1199 patients have been recruited from 92 centres (UK, Georgia, Italy, Malaysia, Switzerland). The objective is to have 80 UK centres and 40 international centres.
Funding: This project is funded by the National Institute for Health Research, HTA Programme (11/129/109)
Disclaimer: The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Health and Technology Assessment Programme, NIHR, NHS or the Department of Health.
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Author Disclosure Block: P.M.W. Bath: None. **J. Appleton:** None. **H. Foster:** None. **M. Adrian:** None. **M. Stringer:** None. **J. Longmate:** None. **J. Keeling:** None. **J. Kirby:** None. **J. Smithson:** None. **P. Scutt:** None. **K. Robson:** None. **N. Sprigg:** None.

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Presentation Number: CTP17

Publishing Title: A European, Multicentre, Phase III, Clinical Trial of Hypothermia for Acute Ischaemic Stroke: EuroHYP-1

Author Block: Philip M Bath, Jennifer Smithson, Univ of Nottingham, Nottingham, United Kingdom; Ken Lees, Univ of Glasgow, Inst of Cardiovascular and Medical Sciences, Glasgow, United Kingdom; Malcolm Macleod, Univ of Edinburgh, Ctr of Clinical Brain Sciences, Edinburgh, United Kingdom; Bart van der Worp, Univ Medical Ctr, Dept of Neurology, Utrecht, Netherlands; Derk W Krieger, Univ of Copenhagen, Dept of Neurology, Copenhagen, Denmark; Jesper Petersson, Skane Univ Hosp, Dept of Neurology, Malmö, Sweden; Dimitre Staykov, Stefan Schwab, Univ of Erlangen, Dept of Neurology, Erlangen, Germany; **Nikola Sprigg**, Univ of Nottingham, Nottingham, United Kingdom

Abstract Body: Background: Cooling is a promising neuroprotective intervention in experimental ischaemic stroke; cooling to 35°C reduced infarct size by about one third. Cooling awake ischaemic stroke patients to 35°C has been shown feasible and safe, but whether this is safe and effective has not been tested in a large clinical trial.2
Aims: To determine whether systemic cooling to target temperature of 34 to 35°C, started within 6 hours of symptom onset and maintained for 12 hours, improves functional outcome at 3 months in patients with acute ischaemic stroke.
Methods: Open, randomised, phase III, multicentre, international clinical trial with masked outcome assessment testing the safety and efficacy of therapeutic cooling in 800 awake adult patients with acute ischaemic stroke.
Cooling will be initiated within 6 hours of symptom onset with an intravenous infusion of 20 ml/kg cooled normal saline (4°C) over 30 to 60 minutes, followed by either surface or endovascular cooling to 34 to 35°C, maintained for 12 hours. Shivering and discomfort will be prevented and treated with anti-shivering drugs. All patients will receive best medical treatment, including alteplase, if indicated. The primary outcome is centrally adjudicated modified Rankin Scale at 90 days (shift analysis). A trial with 400 patients per arm has 80% power to detect a 7% absolute improvement in the mRS at the 5% significance level. As of 30th October 2015, 44 patients have been recruited across 14 sites in 5 countries.
Conclusion: EuroHYP-1 is ongoing, funded by the European Commission 7th Framework Programme (FP7/2007-2013-278709).

Author Disclosure Block: P.M.W. Bath: None. **J. Smithson:** None. **K. Lees:** None. **M. Macleod:** None. **B. van der Worp:** None. **D.W. Krieger:** None. **J. Petersson:** None. **D. Staykov:** None. **S. Schwab:** None. **N. Sprigg:** None.

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Presentation Number: CTP18

Publishing Title: Secondary Stroke Prevention by Uniting Community and Chronic Care Model Teams Early to End Disparities: The SUCCEED Trial

Author Block: Amytis Towfighi, Univ of Southern California; Rancho Los Amigos Natl Rehabilitation Ctr;, Los Angeles, CA; Monica Ayala-Rivera, Theresa Sivers-Teixeira, Rancho Los Amigos Natl Rehabilitation Ctr, Los Angeles, CA; Elizabeth Mojarro-Huang, Los Angeles County-Univ of Southern California Medical Ctr, Los Angeles, CA; Magaly Ramirez, Univ of Southern California, Los Angeles, CA; Heather McCreath, Univ of California at Los Angeles, Los Angeles, CA; Jeremy Wacksman, Dimagi, Inc., Los Angeles, CA; Eric M. Cheng, Univ of California at Los Angeles; Veterans Admin Greater Los Angeles Healthcare System, Los Angeles, CA; Jamie Tran, Olive View-UCLA Medical Ctr, Sylmar, CA; Ana Montoya, 6Olive View-UCLA Medical Ctr, Sylmar, CA; Marilyn Corrales, Rancho Los Amigos Natl Rehabilitation Ctr, Los Angeles, CA; Nerses Sanossian, Univ of Southern California; Los Angeles Count - Univ of Southern California Medical Ctr, Los Angeles, CA; Ali Razmara, Univ of California at Irvine, Irvine, CA; Robert Bryg, Neal Rao, Univ of California at Los Angeles; Olive View-UCLA Medical Ctr, Los Angeles, CA; Bijal Mehta, Univ of California at Los Angeles; Harbor-UCLA Medical Ctr, Los Angeles, CA; Tara Dutta, Univ of Southern California; Rancho Los Amigos Natl Rehabilitation Ctr;, Los Angeles, CA; Shlee Song, Cedars-Sinai Medical Ctr, Los Angeles, CA; Shinyi Wu, Univ of Southern California, Los Angeles, CA; Phyllis Willis, Watts Labor Community Action Committee, Los Angeles, CA; Lilian Moreno, Rancho Los Amigos Natl Rehabilitation Ctr, Los Angeles, CA; Beatrice Martinez, Rancho Los Amigos Natl Rehabilitation Ctr; Harbor-UCLA Medical Ctr, Los Angeles, CA; Cynthia Munoz, Rancho Los Amigos Natl Rehabilitation Ctr, Los Angeles, CA; Mireya Macias, Tom Bailey, Worker Education and Resource Ctr, Los Angeles, CA; Adam Richards, Frances Barry, Univ of California at Los Angeles, Los Angeles, CA; Valerie Hill, Univ of Southern California; Rancho Los Amigos Natl Rehabilitation Ctr;, Los Angeles, CA; Brian Mittman, Veterans Admin Greater Los Angeles Healthcare System, Los Angeles, CA; William Cunningham, Honghu H Liu, David Ganz, Univ of California at Los Angeles, Los Angeles, CA; Diane Factor, Worker Education and Resource Ctr, Los Angeles, CA; Lillie Hudson, Rancho Los Amigos Natl Rehabilitation Ctr, Los Angeles, CA; Barbara G. Vickrey, Univ of California at Los Angeles; Veterans Admin Greater Los Angeles Healthcare System; Icahn Sch of Med at Mount Sinai, New York, NY

Abstract Body: Background: Recurrent stroke risk is substantially reduced by controlling hypertension, diet, physical activity, dyslipidemia, and smoking; yet these are sub-optimally controlled in most stroke survivors, particularly among indigent, minority populations with barriers to accessing care.
Objective: To develop and test the impact of a care manager (CM)-community health worker (CHW) team intervention on blood pressure (BP) control among adults with recent stroke/ TIA, enrolled from the largest US municipal safety-net health system.
Design: Randomized-controlled trial.
Population Studied: 500 adults, recruited from 4 Los Angeles County-Department of Health Services hospitals. Inclusion criteria: >40 yrs, ischemic/hemorrhagic stroke or TIA (< 90 days), English-/Spanish-/Cantonese-/Mandarin-/Korean-speaking. Exclusion criteria: systolic BP <120 mmHg, inability to provide informed consent.

Intervention:
Participants randomized to intervention are managed by a CM (Nurse Practitioner or Physician Assistant)-CHW team, receive self-management tools (including goal cards and BP monitors), ≥3 clinic visits, ≥3 home visits, and the opportunity to participate in CHW-facilitated Chronic Disease Self-Management classes. The team uses evidence-based protocols to: (1) manage vascular risk factors; (2) teach/reinforce self-management skills; (3) promote a healthy lifestyle; (4) increase stroke knowledge; (5) assist in healthcare system navigation, and (6) assess for/address social isolation and depression. CommCare, a web-based application, enables CMs/CHWs to communicate, manage panels, access protocols/scripts, and track tasks. Participants randomized to control receive usual care and stroke risk factor handouts.
Outcomes Measurements: Primary: Systolic BP control. Secondary: other vascular risk factor control, stroke literacy, medication adherence.
Analysis: Intention-to-treat analysis to determine effectiveness of intervention at 12 months, cost analysis, and sustainability plan.
Trial Status: Enrolling

Author Disclosure Block: **A. Towfighi:** Research Grant; Significant; This research trial was funded through NIH. **M. Ayala-Rivera:** None. **T. Sivers-Teixeira:** None. **E. Mojarro-Huang:** None. **M. Ramirez:** None. **H. McCreath:** None. **J. Wacksman:** None. **E.M. Cheng:** None. **J. Tran:** None. **A. Montoya:** None. **M. Corrales:** None. **N. Sanossian:** None. **A. Razmara:** None. **R. Bryg:** None. **N. Rao:** None. **B. Mehta:** None. **T. Dutta:** None. **S. Song:** None. **S. Wu:** None. **P. Willis:** None. **L. Moreno:** None. **B. Martinez:** None. **C. Munoz:** None. **M. Macias:** None. **T. Bailey:** None. **A. Richards:** None. **F. Barry:** None. **V. Hill:** None. **B. Mittman:** None. **W. Cunningham:** None. **H.H. Liu:** None. **D. Ganz:** None. **D. Factor:** None. **L. Hudson:** None. **B.G. Vickrey:** Research Grant; Significant; This research trial was funded through NIH.

Presentation Number: CTP19

Publishing Title: New Generation Hydrogel Endovascular Aneurysm Treatment Trial

Author Block: Jennifer D Ward, Byron K Yip, Northwestern Univ, Chicago, IL; Rami J Aoun, Mithum G Sattur, Bernard R Bendok, Mayo Clinic, Phoenix, AZ

Abstract Body: Background: Endovascular treatment of intracranial aneurysms has seen significant advances. One major limitation of the endovascular approach is durability of treatment and aneurysm recanalization. To address this issue, one approach was the development of hydrogel-coated coils. Hydrogel expands upon exposure to blood and thus enhances coil packing density. Higher initial coil packing density may potentially result in lower rates of recurrence.
Hypothesis: The 2nd Generation HydroCoil Embolic System allows for a higher packing density, higher initial occlusion, lower recanalization, and lower retreatment rates compared to bare platinum coils.
Objective: To compare clinical and angiographic outcomes (initial complete occlusion, recanalization, retreatment, and adverse event rates) in patients receiving the 2nd Generation HydroCoil Embolic System versus patients receiving bare platinum coils.
Methods: This is a randomized, controlled, multicenter, post-market clinical trial. Subjects between 18 and 75 years of age with ruptured or unruptured intracranial aneurysms (3-14 mm in size) who are amenable to endovascular treatment are randomly assigned 1:1 to one of two treatment arms: 1) the HydroCoil Embolic System (HES), or 2) bare platinum coils. No bioactive coils, 1st generation HydroCoils or liquid embolics are allowed in the study. In the HES arm, up to 10% of total coil length using bare platinum is allowed if deemed necessary by the investigator. Any type of bare platinum coil may be utilized in the bare platinum arm. Assist-devices can be used at the discretion of the investigator. The duration of the open enrollment phase will be 24 months or until the required number of subjects are enrolled (n = 600). Each subject will have a post-procedure follow-up of at least 18 months. Subjects will be recruited from up to 50 national and international centers. Each Investigational Site will be expected to enroll at least 20 Subjects.
Results: A total of 567 patients have been enrolled to date in the study. The study is still ongoing.
Conclusions: A limitation of endovascular aneurysm treatment is recurrence. This trial aims to answer the question of whether the new generation hydrogel coil reduces recurrence rates when compared to bare platinum coils.

Author Disclosure Block: J.D. Ward: None. **B.K. Yip:** None. **R.J. Aoun:** None. **M.G. Sattur:** None. **B.R. Bendok:** None.

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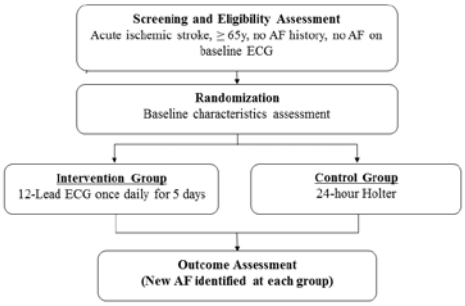
Presentation Number: CTP20

Publishing Title: Atrial Fibrillation Trial to Evaluate Real-world Procedures for Unearthing Its Location After Stroke Events (AFTER-PULSE): Study Protocol

Author Block: Meng Lee, Chang Gung Univ and Chang Gung Memorial Hosp, Puzi, Taiwan; Wen-Yi Huang, Chang Gung Univ and Chang Gung Memorial Hosp, Keelong, Taiwan; Sung-Chun Tang, Natl Taiwan Univ Hosp, Taipei, Taiwan; Sheng-Feng Sung, Chiayi Christian Hosp, Chiayi, Taiwan; Jann-Der Lee, Chang Gung Univ and Chang Gung Memorial Hosp, Puzi, Taiwan; Tsong-Hai Lee, Chang Gung Univ and Chang Gung Memorial Hosp, Linkou, Taiwan; Yung-Sung Huang, Buddhist Dalin Tzu Chi General Hosp, Chiayi, Taiwan; Jiann-Shing Jeng, Natl Taiwan Univ Hosp, Taipei, Taiwan; Chang-Min Chung, Yi-Ling Wu, Chang Gung Univ and Chang Gung Memorial Hosp, Puzi, Taiwan; Bruce Ovbiagele, Medical Univ of South Carolina, Charleston, SC

Abstract Body: Background: Enhancing detection of undiagnosed atrial fibrillation (AF) in hospitalized patients with a recent ischemic stroke is important because of the treatment implications; especially since presence of paroxysmal AF may not be picked up in a single 12-lead electrocardiogram (ECG) test. While several trials have shown improved detection of AF with prolonged ECG monitoring, this strategy is associated with relatively high cost, labor intensity, and patient inconvenience, thereby making it challenging to routinely implement in all hospitals. Fortunately, conventional 24-hour Holter monitoring and repeated 12-lead ECGs are readily available to detect paroxysmal AF in all hospitals, but is unclear which is the better strategy for evaluating undiagnosed AF. The objective of his study is to conduct a randomized trial of serial 12-lead ECGs vs. 24-hour Holter monitoring in the detection of AF in ischemic stroke patients without known AF.
Methods/Design: We plan to enroll 600 participants from six hospitals in Taiwan. Patients will be eligible for enrollment if they are admitted for an acute ischemic stroke within 7 days, are≥ 65 years of age, and have no known AF by history or on baseline ECG at admission. We will randomly assign participants in a 1:1 ratio to undergo daily 12-lead ECG once daily for 5 days (intervention group) or 24-hour Holter monitoring (control group). Primary outcome is newly detected AF on a 12-lead ECG orAF lasting ≥30 seconds on Holter monitoring. Secondary outcomes included episodes of AF on a 12-lead ECG or AF with any duration on Holter monitoring.
Discussion: The results of the trial will help to decide which of these routinely available strategies is

more effective for the detection of undiagnosed paroxysmal AF in elderly patients with a recent



ischemic stroke.

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Presentation Number: CTP21

Publishing Title: Tailored Hospital-based Risk Reduction to Impede Vascular Events After Stroke (THRIVES)

Author Block: Bruce Ovbiagele, Medical Univ of South Carolina, Charleston, SC; Rufus Akinyemi, Oyedunni Arulogun, Univ of Ibadan, Ibadan, Nigeria; Mulugeta Gebregziabher, Raelle Saulson, Medical Univ of South Carolina, Charleston, SC; Ezinne Uvere, Mayowa Owolabi, Univ of Ibadan, Ibadan, Nigeria; THRIVES Investigators

Abstract Body: Background: Stroke is the second-leading cause of death in low- and middle-income countries, but use of evidence-based therapies for stroke prevention in such countries, especially those in Africa, is extremely poor. This study is designed to enhance the implementation and sustainability of secondary stroke-preventive services following hospital discharge.
Objective: To test whether a bundled Chronic Care Model-based initiative will significantly improve blood pressure control after stroke.
Design: Prospective randomized controlled trial with blinded endpoint adjudication.
Population Studied: 400 patients with a recent stroke discharged from four medical care facilities in Nigeria.
Interventions: Culturally-appropriate, system-relevant, multipronged tool comprising the use of a patient report card, an educational video, and text-message based coordination of post-hospitalization care.
Outcome Measures: Primary outcome is improvement of blood pressure control at one year. Secondary endpoints include control of other stroke risk factors, medication adherence, functional status, and quality of life.
Analysis: A general linear regression model will be used to determine if the THRIVES intervention will produce a greater decrease in SBP from baseline compared with standard care at the end of the intervention period (12 months).
Trial Status: Ongoing. So far, the study has screened 249 people and enrolled 207 participants.
PI/Coordinator Name(s): Bruce Ovbiagele/Raelle Saulson
PI/Coordinator Affiliation(s): Medical University of South Carolina
Trial Sponsor(s): NIH-NINDS
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Author Disclosure Block: B. Ovbiagele: Research Grant; Modest; NIH-NINDS U01 NS079179-01, NHGRI, NIH-NINDS U54 HG007479, NIH-NINDS R21 NS094033. **R. Akinyemi:** Research Grant; Significant; U01 NS079179. **O. Arulogun:** Research Grant; Significant; U01 NS079179. **M. Gebregziabher:** Research Grant; Significant; U01 NS079179. **R. Saulson:** Research Grant; Significant; U01 NS079179. **E. Uvere:** Research Grant; Significant; U01 NS079179. **M. Owolabi:** Research Grant; Significant; U01 NS079179.

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Presentation Number: CTP22

Publishing Title: Extending the Time for Thombolysis in Emergency Neurological Deficits - The EXTEND Trial

Author Block: Henry Ma, Florey Neuroscience and Mental Health Insts and Monash Univ, Melbourne, Victoria, Australia; Bruce C Campbell, Dept of Med, Royal Melbourne Hosp, Univ of Melbourne, Melbourne, Victoria, Australia; Mark Parsons, Chris Levi, Priority Res Ctr for Brain and Mental Health Res, John Hunter Hosp, Univ of Newcastle, Newcastle, NSW, Australia; Leonid Churilov, Florey Neuroscience and Mental Health Insts, Melbourne, Victoria, Australia; Chung Y Hsu, Dept of Neurology, China Medical Univ and Graduate Inst of Clinical Medical Science, China Medical Univ, Taichung, Taiwan; Stephen M Davis, Dept of Neurology, Royal Melbourne Hosp, Univ of Melbourne, Melbourne, Victoria, Australia; Geoffery A Donnan, Florey Neuroscience and Mental Health Insts, Melbourne, Victoria, Australia; EXTEND Investigators

Abstract Body: Background: Current clinical application of thrombolysis in stroke is limited by the 4.5hour time window and not applicable to patients with wake up stroke (WUS). Patient selection using advanced penumbral imaging criteria may allow extension of the therapeutic window.
Objective: To test the hypothesis that perfusion-diffusion mismatch can be used to select patients with favourable response to thrombolysis beyond conventional time windows.
Design: EXTEND is an investigator-initiated, randomised, double-blind, placebo controlled trial of intravenous alteplase vs placebo in patients with ischemic stroke 4.5-9 hours from stroke onset and WUS.
Methods: Patients with ischemic stroke within 4.5-9 hours from stroke onset and WUS patients, (WUS defined as the midpoint between time to sleep and awakening with the stroke symptoms less than 9 hours), are eligible for recruitment (n=200). Criteria for entry into the trial include perfusion-ischemic core mismatch using a perfusion threshold of Tmax more than 6sec and a perfusion-ischemic core lesion volume ratio of more than 1.2 and absolute mismatch more than 10mL. Ischemic core lesion volume must be less than 70mL. This will be assessed using a fully automated software package (RAPID, Stanford University). Reperfusion/recanalization will be assessed at 24 hours. Safety endpoints include symptomatic intracerebral haemorrhage and death.
Outcome measures: The primary endpoint is mRS 0-1 at 90 days. Secondary endpoints will include mRS ordinal analysis, reperfusion, recanalization, quality of life and depression scales.
Trial status: Recruitment is underway in Australasia, Taiwan and Finland. As of October 2015,118 patients (median age 78.0 years (IQR 66.5, 82.0), NIHSS 14 (IQR 8, 18) were randomised and a prospective pooled meta-analysis with ECASS4-EXTEND is planned.

Author Disclosure Block: H. Ma: Consultant/Advisory Board; Modest; Astra Zeneca. **B.C.V. Campbell:** None. **M. Parsons:** None. **C. Levi:** None. **L. Churilov:** None. **C.Y. Hsu:** None. **S.M. Davis:** None. **G.A. Donnan:** Honoraria; Modest; Pfizer, Boerhinger, Sanofi, Bayer.

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Presentation Number: CTP23

Publishing Title: Intracerebral Hemorrhage Deferoxamine Trial

Author Block: Caroline Feigert, Beth Israel Deaconess Medical Ctr, Boston, MA; Sharon Yeatts, Medical Univ of South Carolina, Charleston, SC; Claudia Moy, NINDS, Bethesda, MD; Aaron Perlmutter, Andre Thornhill, Catherine Dillon, Lydia Foster, Medical Univ of South Carolina, Charleston, SC; Magdy Selim, Beth Israel Deaconess Medical Ctr, Boston, MA

Abstract Body: BACKGROUND: The iron chelator, Deferoxamine Mesylate (DFO), exerts diverse neuroprotective effects, reduces perihematoma edema and neuronal damage, and improves functional recovery after experimental ICH. To translate these findings into the clinical setting, we conducted a small Phase I, open-label study to determine the tolerability, safety, and maximum tolerated dose of DFO in patients with ICH, then initiated this Phase II clinical trial.
OBJECTIVES: 1) To assess whether it is futile to move DFO into Phase III evaluation as a therapeutic intervention for ICH; and 2) To assess the safety of DFO in a larger cohort of patients.
METHODS: This is a prospective, multi-center, double-blind, randomized, placebo-controlled, phase-II clinical trial. Approximately, 294 subjects with spontaneous ICH will participate in this study. Participants will be randomized to either DFO at 32 mg/kg/day (up to a maximum daily dose of 6000 mg/day), or saline placebo, given by IV infusion for 3 consecutive days. Treatment will be initiated within 24 hours after ICH symptom onset. Randomization will control baseline imbalances associated with ICH onset-to-treatment time, baseline ICH score, ICH volume, and NIHSS score, and warfarin use. All subjects will be followed for 6 months.
OUTCOME MEASURES: The primary outcome measure is the modified Rankin Scale (mRS), dichotomized to define good functional outcome as mRS score of 0-2 at 90 days. At the conclusion of the study, the proportion of DFO-treated subjects with mRS 0-2 at 3 months will be compared to the placebo proportion in a futility analysis. As secondary analyses of the primary outcome, a dichotomized analysis considering the proportion of DFO- and placebo-treated subjects with mRS 0-3 (still a desirable effect in patients with ICH) will also be performed. Similar analyses at 180 days and ordinal analysis across all mRS scores will be performed. Safety endpoints will include all DFO-related adverse events until day-7 or discharge (whichever is earlier) and serious adverse events through day-90. Mortality (all cause and ICH-related) will be assessed through day 180.
TRIAL STATUS: Enrollment in iDEF began in the Fall of 2014 and 86 subjects have been enrolled as of 10/28/2015.

Author Disclosure Block: C. Feigert: None. **S. Yeatts:** Consultant/Advisory Board; Significant; Genentech. **C. Moy:** Employment; Significant; NINDS. **A. Perlmutter:** None. **A. Thornhill:** None. **C. Dillon:** None. **L. Foster:** None. **M. Selim:** Research Grant; Significant; NIH/NINDS.

Presentation Number: CTP24

Publishing Title: Rapid Intervention With Glyceryl Trinitrate in Hypertensive Stroke Trial-2 (RIGHT-2): Safety and Efficacy of Transdermal Glyceryl Trinitrate, a Nitric Oxide Donor

Author Block: Mark Dixon, Jason Appleton, Timothy England, Diane Havard, Harriet Howard, Univ of Nottingham, Nottingham, United Kingdom; Malcolm Jarvis, Patient public representative on behalf of Univ of Nottingham, Nottingham, United Kingdom; Alan Montgomery, Univ of Nottingham, Nottingham, United Kingdom; Stuart Pocock, London Sch of Hygiene and Tropical Med, Dept of Medical Statistics, London, United Kingdom; John Potter, Univ of East Anglia, Norwich Medical Sch, Norwich, United Kingdom; Christopher Price, Univ of Newcastle, The Medical Sch, Newcastle, United Kingdom; Tom Robinson, Univ Hosp of Leicester, Dept of Cardiovascular Sciences, Leicester, United Kingdom; Christine Roffe, Keele Univ, Inst of Science and Technology in Med, Keele, United Kingdom; Niro Siriwardena, Univ of Lincoln, Sch of Health and Social Care, Nottingham, United Kingdom; Nikola Sprigg, Univ of Nottingham, Nottingham, United Kingdom; Joanna M Wardlaw, Univ of Edinburgh, Ctr for Clinical Brain Sciences, Edinburgh, United Kingdom; Philip M Bath, **Polly Scutt**, Univ of Nottingham, Nottingham, United Kingdom

Abstract Body: Rationale:
High blood pressure (BP) is common in acute stroke and is associated with poor outcome. Previous hospital-based trials testing the effects of BP lowering on functional outcome have been inconclusive. The PIL-FAST and RIGHT pilot trials confirmed the feasibility of performing single-centre ambulance-based stroke trials in the UK. In both RIGHT and a subgroup of patients recruited within 6 hours into the large ENOS trial, transdermal glyceryl trinitrate (GTN), a nitric oxide donor, lowered BP and reduced death or disability. Based on these results, RIGHT-2 aims to test the safety and efficacy of transdermal GTN in the pre-hospital setting.
Methods
Paramedics from 7 UK ambulance services serving 40 comprehensive or primary stroke care centres will screen, consent, randomise and treat 850 patients presenting within 4 hours of FAST-positive stroke and with systolic BP >120 mmHg. Treatment will comprise GTN or similar sham patch, and will be continued in hospital for 3 days. The primary outcome will be the modified Rankin Scale at day 90. Secondary outcomes include vascular events, disability, quality of life, mood and cognition. Neuroimaging and biomarkers will examine potential mechanisms of action. Recruitment will commence in quarter 4 2015.
Funding: British Heart Foundation

Author Disclosure Block: M. Dixon: None. **J. Appleton:** None. **T. England:** None. **D. Havard:** None. **H. Howard:** None. **M. Jarvis:** None. **A. Montgomery:** None. **S. Pocock:** None. **J. Potter:** None. **C. Price:** None. **T. Robinson:** None. **C. Roffe:** None. **N. Siriwardena:** None. **N. Sprigg:** None. **J.M. Wardlaw:** None. **P.M.W. Bath:** None. **P. Scutt:** None.

Presentation Number: CTP25

Publishing Title: Hospital Processes Reengineering of Intravenous Thrombolysis in Acute Ischemic Stroke in China: PROMISE-CHINA

Author Block: Dawei Dong, Mu Li, Yusheng Zhang, Lian Huang, The First Affiliated Hosp of Jinan Univ, Guangzhou, China; Yilong Wang, Liping Liu, Beijing Tiantan Hosp of Capital Medical Univ, Beijing, China; Yongjun Wang, Beijing Tiantan Hosp of Capital Medical Univ, Beijing, China; **Anding Xu**, The First Affiliated Hosp of Jinan Univ, Guangzhou, China

Abstract Body: Background and Purpose: Intravenous tissue plasminogen activator (tPA) in acute ischemic stroke (AIS) is recommended and its benefit is time-dependent. Furthermore, the feasibility and effectiveness of door-to-needle times (DNT) ≤ 60 min has been proved. However, only about 10% of AIS patients within time window received tPA in China, with a very low rate of DNT ≤ 60 minutes. Using business processes reengineering (BPR) theory, we try to increase the intravenous thrombolysis rate, and shorten DNT for AIS patients in Chinese hospitals.
Trail design: This trial is a prospective, multi-center, longitudinal, non-randomized intervention study. According to BPR theory, a set of hospital processes reengineering strategies for intravenous tPA was made by the trial academic committee. This trial was planned to recruit 30-40 hospitals with an estimated patient sample size of 3600 from July 2014 to June 2015. All AIS patients arrived at hospital within 3.5 hours of the onset would be consecutively enrolled. The data of the first 3-month, the published results of Chinese National Stroke Registry (CNSR), were used as the baseline, respectively. The initial program goal is to achieve a thrombolysis rate and DNT ≤ 60 min rate at least 20% (doubled as compared with the CNSR results), and the rates to be increased by 40% as compared with the baseline.
Trial Current state and preliminary results: Thirty-four hospitals were recruited, and 2178 patients were enrolled in the study. The last patient was enrolled on Jun 30 2015, and the follow-up was finished on Sep 30 2015. The CRF query is being performed and statistic analysis is to be done after the query. Preliminary results show that 62.2% (1355/2178) of the patients received tPA, the median DNT was 65 minutes (interquartile range, 54-90), the proportion of DNT ≤ 60 minutes was 45.5% (587/1290).
Conclusions: PROMISE-CHINA is a prospective multicenter clinical trial, aiming to improve the care quality for AIS patients. The preliminary results demonstrated the hospital processes reengineering strategies for thrombolysis in China is feasible.

Author Disclosure Block: **D. Dong:** None. **M. Li:** None. **Y. Zhang:** None. **L. Huang:** None. **Y. Wang:** None. **L. Liu:** None. **Y. Wang:** None. **A. Xu:** None.

Presentation Number: CTP26

Publishing Title: An Interim Analysis of the SAfety and Effectiveness of the Treatment of Wide Neck, Saccular IntracraniaL Aneurysms With the Neuroform Atlas™ Stent System Trial. On Behalf of the ATLAS Trial Investigators

Author Block: Osama O Zaidat, St. Vincent Mercy Hosp, Toledo, OH; Brian Jankowitz, Univ of Pittsburgh, Pittsburgh, PA

Abstract Body: Background:
Trans-arterial stent-assisted coil embolization of wide-neck aneurysms is a commonly used endovascular approach; however, the use of adjunctive stent systems is currently only available under a Humanitarian Device Exemption (HDE) pathway. The Neuroform Atlas stent is a new iteration of the current HDE-approved Neuroform™ stent, designed to provide improved stent conformability, scaffolding, trackability, and miniaturization of the delivery system. Here, we present interim demographic and technical results of the ongoing SAfety and Effectiveness of the Treatment of Wide Neck, Saccular IntracraniaL Aneurysms with the Neuroform Atlas™ Stent System (ATLAS) Trial.
Study Design:
ATLAS is a prospective, open-label, single-arm study, with 25 US sites. Enrollment will include 124 evaluable subjects. Key inclusion criteria: subjects with a wide-neck aneurysm, baseline mRS≤3, 18-80 years of age. Key exclusion criteria: subjects with multiple aneurysms and prior stent-assisted coiling at the target aneurysm. Primary efficacy end-point: rate of complete aneurysm occlusion on 12-month angiogram. Primary safety end-point: any ipsilateral stroke or neurological death within 12 months.
Results:
To date, 43 subjects were enrolled and 34 had data available for analysis. Mean age was 59.8 ± 11.7 years, 84% women. Location: anterior circulation (80%), anterior communicating aneurysms were most common (48%). Size: two-thirds were 3.1-7mm in maximum diameter versus 10% >10mm. The stent deployment success rate was 100%. Packing density (PD) correlated inversely with aneurysm size. For aneurysms 3.1-7mm vs. aneurysms >10mm, PD was 29% vs. 12% ($p=0.005$) in the anterior circulation and 38% vs. 3% ($p<0.0001$) in the posterior circulation. For aneurysm type, bifurcation vs. sidewall, PD was 21% vs. 34% in the anterior circulation and 24% vs. 12% in the posterior circulation.
Conclusion:
ATLAS is an ongoing stent-assisted aneurysm coiling trial, utilizing a next generation microstent with a 100% success rate of deployment and PD of 29% and 38% in anterior circulation and posterior circulation aneurysms 3.1-7 mm, respectively.

Author Disclosure Block: O.O. Zaidat: Research Grant; Modest; Target registry, track registry, ATLAS. Consultant/Advisory Board; Modest; Stryker Neurovascular, Medtronic, Penumbra, Neuravi. **B. Jankowitz:** Consultant/Advisory Board; Modest; ATLAS.

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Presentation Number: CTP27

Publishing Title: THE PRISMS TRIAL: A Phase 3b, Double-blind, Multicenter Study to Evaluate the Efficacy and Safety of Alteplase in Patients With Mild Stroke

Author Block: Pooja Khatri, Univ of Cincinnati, Cincinnati, OH; The PRISMS Collaborators

Abstract Body: BACKGROUND: Mild stroke represents a large proportion of all ischemic strokes. The balance of risk versus benefit of thrombolysis for acute ischemic stroke patients with mild deficits at the time of the treatment decision is uncertain.
OBJECTIVE: To determine the efficacy and safety of IV alteplase for treatment of acute ischemic stroke (AIS) in patients with mild stroke ("rapidly improving stroke symptoms" and "minor neurologic deficit").
DESIGN: PRISMS is a double-blind, multicenter, randomized, phase 3b trial of patients with mild ischemic stroke within 3 hours of last known well time. Mild stroke is defined as a National Institutes of Health Stroke Scale (NIHSS) ≤5 and not "clearly disabling" (i.e., inability to return to work or perform basic activities of daily living based on current deficits). Patients meeting eligibility criteria are randomized (1:1) to receive either (1) IV alteplase 0.9 mg/kg with oral aspirin placebo or (2) IV alteplase placebo with oral aspirin 325 mg.
SAMPLE SIZE: Approximately 948 patients will be enrolled across the United States.
PRIMARY OUTCOME MEASURE: Difference in proportion of a favorable functional outcome (modified Rankin Scale score of 0 or 1) between the two treatment groups at 90 days post-randomization.
STATISTICAL ANALYSIS: The primary efficacy outcome will be analyzed via a Cochran-Mantel-Haenszel test, stratified by pre-treatment NIHSS score (0-2 vs 3-5), age (<65 vs ≥65), and last known well time to treatment (0-2 hours vs 2-3 hours).
TRIAL STATUS: First Patient In (FPI) was May 1st, 2014. As of October 31st, 2015, 167 patients were enrolled. The trial continues to accelerate with its highest enrollment in the most recent month of October (n=20).

Author Disclosure Block: P. Khatri: Other Research Support; Significant; Genentech pays UC Neurology Dept for my effort as Lead PI of PRISMS Trial, Penumbra pays UC Neurology Dept for my effort as Lead Neuro PI of THERAPY Trial. Expert Witness; Modest; Medicolegal consultation. Consultant/Advisory Board; Modest; Grand Rounds Experts, Inc (online clinical consultation). Other; Modest; UpToDate, Inc (royalties for online publication).

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Presentation Number: CTP28

Publishing Title: DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake Up and Late Presenting Strokes Undergoing Neurointervention

Author Block: Raul G Nogueira, Emory Univ Sch of Med, Atlanta, GA; Christine C Yang, Amelia J Saliba, Stryker Neurovascular, Fremont, CA; DAWN Trialists; Tudor G Jovin, Univ of Pittsburgh Medical Ctr, Pittsburgh, PA

Abstract Body: Trial Abbreviation: DAWN. DWI or CTP **A**ssessment with Clinical Mismatch in the Triage of **W**ake Up and Late Presenting Strokes Undergoing **N**eurointervention
NCT02142283 (ClinicalTrials.gov)
Background: Whether the treatment window for endovascular therapy can be expanded in properly selected patients remains to be established.
Objective: to evaluate the hypothesis that Trevo thrombectomy plus medical management leads to superior clinical outcomes at 90 days as compared to medical management alone.
Design: multi-center, prospective, randomized, controlled, blinded-endpoint, phase II/III (feasibility/pivotal) trial of thrombectomy for wake-up and late presenting AIS that follows an adaptive design based on Bayesian predictive probabilities allowing population enrichment.
Population Studied and Intervention: Subjects presenting 6-24 hours from TLSW with CTA or MRA proven occlusion of the intracranial ICA or MCA-M1 are randomized in a 1:1 ratio to embolectomy vs. medical therapy. Selection is based on clinical-core mismatch (CCM) and age: 0-20 cc core, NIHSS ≥ 10 and age ≥ 80; 0-30 cc core, NIHSS ≥ 10 and age < 80 years old; 31 cc to < 50 cc core, NIHSS ≥ 20 and age < 80. Core is measured with RAPID software on DWI MRI or CT Perfusion. Randomization is stratified by CCM subgroups, TLSW to Treatment, and Occlusion Site. First interim analysis at 150 patients. The maximum sample size is 500.
Outcome Measures & Analysis: primary endpoint: average weighted 90-day mRS. Secondary endpoints: good outcome at 90 days, “early response” at day 5-7, all-cause mortality, median final infarct size, revascularization at 24 hours, symptomatic ICH.
Trial Status: Enrollment started in September 2014. As of November 2015, a total of 55 patients have been randomized across seven centers. A total of 12 U.S. centers are actively enrolling. Another 19 sites are pending activation including 11 in the U.S., 2 in Spain, 2 in France, 2 in Germany, one in Canada, and one in Australia.

Author Disclosure Block: R.G. Nogueira, None; **C.C. Yang**, Sponsor (Stryker Neurovascular), Significant,Employment; **A.J. Saliba**, Sponsor (Stryker Neurovascular), Significant,Employment; **T.G. Jovin**, Stryker, Modest,Consultant/Advisory Board; Stryker Study PI, Modest,Other.

Presentation Number: CTP29

Publishing Title: Swipe out Stroke: Feasibility of Using Mobile Health Technology to Address the Obesity Disparity in Minority Populations

Author Block: Nneka L Ifejika, Farhaan Vahidy, Munachi N Okpala, Elizabeth A Noser, Chunyan Cai, UTHSC Houston, Houston, TX; James C Grotta, Mischer Neuroscience Inst; Memorial Hermann Hosp - Texas Medical Ctr, Houston, TX; Sean I Savitz, UTHSC Houston, Houston, TX

Abstract Body: Background: Obesity is a condition that disproportionately affects minorities and is highly correlated with cerebrovascular disease. Unfortunately, structured weight loss programs are expensive, and compliance significantly decreases upon program completion. Mobile health (mHealth) technology is an innovative, cost-effective way to bridge this gap. Minorities spend over 4.5 billion dollars annually on consumer electronics, making studies that utilize mHealth applications ideal for health promotion and disease prevention.
Objectives: SoS uses a physician monitored mHealth obesity intervention to test the following:
1. Feasibility, administration and adherence.
2. Early risk factor diagnosis in obese caregivers and first degree family members.
3. Estimation and comparison of effect sizes for changes in BMI, systolic blood pressure, serum lipids, Hemoglobin A1c and Factor VIII levels.
Design: Prospective Randomized Controlled Trial with Open Blinded Endpoint (PROBE).
Population: Fifty African-American or Hispanic ischemic or hemorrhagic stroke patients and fifty caregivers/family members (>18 years of age) with a BMI greater than 30 kg/m2, recruited from one TJC accredited comprehensive stroke center.
Intervention: Six month mHealth intervention using caloric restriction, dietary counseling, positive reinforcement, reminder messages for missed days (Months One to Three) and weekly summary of goals (Months Two to Six).
Control group receives food journals and usual care.
Outcome Measures:
1. Adherence to the mHealth intervention.
2. Percent loss of total body weight.
Analysis: Regression analysis to determine whether the mHealth intervention group achieved better outcomes than usual care, adjusting for age, stroke severity and gender. Factors that impact compliance (depression, loneliness, employment, access to transportation) will be compared by treatment group.
Current Status: Swipe out Stroke enrollment began in January 2015 and is ongoing.

Author Disclosure Block: N.L. Ifejika: Research Grant; Significant; NIH/NCATS UL1 TR000371, NIH/NINDS Diversity Supplement to P50 NS 044227 University of Texas Specialized Program of Translational Research in Acute Stroke (SPOTRIAS).. **F. Vahidy:** None. **M.N. Okpala:** None. **E.A. Noser:** None. **C. Cai:** Research Grant; Significant; NIH/NCATS UL1 TR000371;NIH/NINDS Diversity Supplement to P50 NS 044227 University of Texas SPOTRIAS Grant. **J.C. Grotta:** None. **S.I. Savitz:** None.

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Presentation Number: CTP30

Publishing Title: NIH StrokeNet Trial Proposal Process

Author Block: Joseph P Broderick, Univ of Cincinnati, Cincinnati, OH; Yuko Y. Palesch, Wenle Zhao, Medical Univ of South Carolina, Charleston, SC; Claudia S. Moy, Scott Janis, Natl Inst of Neurological Disorders & Stroke, Rockville, MD

Abstract Body: Introduction: The 2012 Stroke Progress Review Group and National Institute of Neurological Disorders and Stroke (NINDS) identified the need for a highly collaborative multi-center stroke trial network infrastructure that would provide a robust, standardized, and accessible infrastructure to facilitate rapid development and implementation of NINDS-funded stroke trials focused on key interventions in stroke prevention, treatment, and recovery. The NIH StrokeNet was fully funded in April 2014, with a National Coordinating Center (NCC), a National Data Management Center (NDMC), and 25 Regional Coordinating Centers. Three working groups (prevention, treatment, and recovery) were established to assist in the development of protocols.
Methods: Protocol Principal Investigators (PPIs) with potential NIH StrokeNet applications submit their concepts to the NINDS scientific representative as well as to the relevant working group for initial discussion. If the project is deemed to be potentially appropriate for NIH StrokeNet, a formal concept proposal is submitted to the NINDS Extramural Science Committee (ESC) for official approval to submit an NIH grant application. If approved, the proposed study is referred to the appropriate working group to assess feasibility and to the NIH StrokeNet NCC and NDMC to assist in developing a final budget. The expected time from approval of concept proposal by the NINDS ESC to grant submission by the PPI is 3 months.
Results: Since May 2014 there have been 18 concept proposals vetted by the working groups. Nine trials have been approved by the NINDS for grant submission. Two trials have been funded, TeleRehabilitation and DEFUSE 3. Five other trials are currently under NIH review and two trials are being revised for resubmission.
Conclusions: The NIH StrokeNet trial proposal process facilitates the submission of high quality stroke trial applications to the NIH.

Author Disclosure Block: J.P. Broderick: Research Grant; Modest; Research Support from Genentech to Department of Neurology for role on Steering Committee of PRISMS study.. Consultant/Advisory Board; Modest; Pfizer. **Y.Y. Palesch:** Consultant/Advisory Board; Modest; DSMB for Brainsgate Ltd Trial. **W. Zhao:** None. **C.S. Moy:** None. **S. Janis:** None.

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Presentation Number: CTP31

Publishing Title: Remote Preconditioning Over Time to Empower Cerebral Tissue (REM-PROTECT) Study

Author Block: Latisha Katie Ali, Johanna L Avelar, UCLA Stroke Ctr, Los Angeles, CA; David S Liebeskind, Neurovascular Imaging Res Core UCLA Dept of Neurology, Los Angeles, CA; Jeffrey L Saver, UCLA Stroke Ctr, Los Angeles, CA

Abstract Body: Background and Objective: Remote ischemic preconditioning (RPreC) activates multiple endogenous cellular and molecular mechanisms that protect brain (and myocardial) tissues against ischemia by applying repetitive short ischemic periods to a patient's limbs. RPreC has shown preliminary signals of efficacy in preventing ischemic stroke in small pilot trials in large artery atherosclerotic stroke and in cerebral vasospasm after subarachnoid hemorrhage. We plan to evaluate RPreC as a novel therapeutic strategy to prevent stroke, progressive ischemic brain injury, and cognitive decline in patients with moderate to severe cerebral small vessel ischemic disease.
Design: This is a single site, feasibility dose-ranging randomized trial of ischemic preconditioning. The study will have a randomized phase and a follow-up phase. 60 enrolled patients will be randomized 2:1 to best standard medical care plus active RPreC for 1 year and then follow-up for 1 year versus best standard medical care alone for 1 year and then active RPreC for 1 year.
Intervention: During periods of active treatment, RPreC will be induced using a device which delivers four remote ischemic conditioning cycles of five minute intervals followed by five-minutes of normal blood flow around both upper body extremities. The RPreC intervention will be add-on therapy to guideline-based best standard medical prevention therapy.
Outcome Measures: Primary outcome measures will be obtained at the end of the first randomized year. Successful completion of this trial will delineate the feasibility and safety. We plan to explore biomarker indicators of potential efficacy, of inducing brain ischemic tolerance by measuring volumetric progression of white matter ischemic injury on diffusion tensor imaging and cognitive battery performance and recurrent stroke events.
Analysis: The primary endpoints are descriptive statistics describing the implementation of the RPreC procedure, including behavioral adherence to treatment, physiologic attainment of limb ischemia, and patient self-reported comfort-discomfort during treatment.
Trial Status: Actively recruiting as of October 2014 (NCT02169739)

Author Disclosure Block: L.K. Ali: None. **J.L. Avelar:** None. **D.S. Liebeskind:** None. **J.L. Saver:** Other; Modest; Clinical Trial Steering Committee St. Jude Medical, Medtronic, BrainsGate, Stryker, BI, Neuravi, Pfizer, SanBio.

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Presentation Number: CTP32

Publishing Title: Extending the time for Thrombolysis in Emergency Neurological Deficits - Australasia Europe (EXTEND-AE)

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Abstract Body: Background: Application of thrombolysis in stroke is limited by the 4.5hour time window and not applicable to patients with wake up stroke (WUS). Patient selection using advanced penumbral imaging criteria may allow extension of the therapeutic window. EXTEND and ECASS4 are investigator initiated, randomised, doubled blinded, placebo controlled studies of intravenous alteplase vs placebo in patients with ischemic stroke 4.5-9 hours from stroke onset and WUS being conducted globally.
Objective: To pool the current data from EXTEND and ECASS4 with ongoing recruitment and endpoint assessment.
Methods: Patients who fulfill the clinical (ischemic stroke within 4.5-9 hours from stroke onset and WUS) and imaging (perfusion-ischemic core mismatch (Tmax>6sec, perfusion-ischemic core lesion volume ratio of >1.2, ischemic core lesion volume <70mL) criteria of the EXTEND trial, will be pooled. Sequential statistical analysis will be performed by an independent statistician for primary endpoint (mRS 0-1 at 90 days) assessment. Trial data will be pooled in a cumulative meta-analysis, with a sequential design applying the triangular test. The need for fixed or random effects models will be determined by heterogeneity and differences in treatment effects between trials. Interim analyses will be performed after every new 25 patients. Recruitment will cease if the triangular boundary is crossed and statistically significant outcomes are obtained for the primary endpoint.
Outcome measures: The primary endpoint is mRS 0-1 at 90 days. Secondary endpoints will include mRS shift analysis, reperfusion, recanalization, and mortality.

Author Disclosure Block: H. Ma: Consultant/Advisory Board; Modest; Astra Zeneca. **P. Ringleb:** None. **C.Y. Hsu:** None. **P.M. Rothwell:** None. **L. Churilov:** None. **B. Campbell:** None. **C. Levi:** None. **M. Parsons:** None. **A. Meretoja:** None. **S.M. Davis:** None. **W. Hacke:** None. **G.A. Donnan:** Honoraria; Modest; Sanofi, Pfizer, Bayer, Boerhinger.

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Presentation Number: CTP33

Publishing Title: The Metoclopramide and Selective Oral Decontamination for Avoiding Pneumonia after Stroke (MAPS-2) Trial: A 2x2 Double-Blind, Randomized Controlled Trial of Metoclopramide and Selective Oral Decontamination for the Prevention of Pneumonia in Patients with Dysphagia After an Acute Stroke

Author Block: Christine Roffe, Univ Hosp of North Midlands NHS Trust, Stoke on Trent, United Kingdom; Tracy Nevatte, Julius Sim, Keele Univ, Keele, United Kingdom; Anushka Warusevitane, Univ Hosp of North Midlands NHS Trust, Stoke on Trent, United Kingdom; Brinton Helliwell, North Staffordshire Combined Healthcare NHS Trust, Stoke on Trent, United Kingdom; Margot Gosney, Royal Berkshire NHS Fndn Trust, Reading, United Kingdom; Benjamin Bray, Kings Coll London, London, United Kingdom; Michael Harrison, Anglia Ruskin Univ, Chelmsford, United Kingdom; Adam Jeans, Salford Royal NHS Fndn Trust, Salford, United Kingdom; Pelham Barton, Univ of Birmingham, Birmingham, United Kingdom; Craig Smith, Salford Royal Fndn NHS Trust, Salford, United Kingdom

Abstract Body: Background: pneumonia is a common complication of stroke and is associated with high mortality, long length of stay and lower potential for functional recovery. Stroke patients who have swallowing problems are more likely to develop pneumonia than stroke patients with normal swallowing function. Patients who require nasogastric feeding are at highest risk of pneumonia.
Rationale: two small pilot studies have shown that metoclopramide and selective oropharyngeal decontamination (SOD), each decrease pneumonia in stroke patients.
Objective: to investigate whether early treatment with metoclopramide or SOD reduces mortality after stoke?
Design: 2x2 factorial double-blind randomised controlled trial.
Population: 1160 adult patients with a clinical diagnosis of acute stroke, within 6 h of presentation to hospital, NIHSS Score ≥ 10, and a failed bedside assessment of swallowing will be recruited from acute stroke units within the UK. Patients will be excluded if there is evidence of vomiting since stroke onset, the patient has pre-existing swallowing problems, probable or definite pneumonia, contraindications or allergies to the trial interventions, or any life-limiting co-morbidities.
Interventions: two interventions are to be tested; the first is metoclopramide, an antiemetic, to be given three times a day and the second is a SOD paste containing 2% colistin, 2% tobramycin and 2% amphotericin B, to be applied four times a day.
Outcome measures: mortality up to the end of the study is the primary outcome measure. Incidence of pneumonia within 14 d, neurological status at 30 d, and disability and quality of life at 90 d are to be included as secondary outcomes. Health economic evaluation will include cost per death avoided and QUALYs gained, both over 90 d.
Analysis: mortality will be compared between groups across the study period using competing risks survival analysis
Trial status: In set-up. ISRCTN pending.

Author Disclosure Block: **C. Roffe:** None. **T. Nevatte:** None. **J. Sim:** None. **A. Warusevitane:** None. **B. Helliwell:** None. **M. Gosney:** None. **B. Bray:** None. **M. Harrison:** None. **A. Jeans:** None. **P. Barton:** None. **C. Smith:** None.

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Presentation Number: CTP34

Publishing Title: Study Protocol of "Worth the Walk": A Randomized Controlled Trial of a Stroke Risk Reduction Walking Intervention Among Minority Hypertensive Seniors in Community Senior Centers

Author Block: Daniel Araiza, Ivy Kwon, Brian Mittman, Honghu Liu, UCLA, Los Angeles, CA; Sarah Song, Rush Univ Medical Ctr, Chicago, IL; Laura Trejo, Los Angeles City Dept of Aging, Los Angeles, CA; Phyllis Willis, Watts Labor Community Action Committee, Los Angeles, CA; John Kotick, Saint Barnabas Senior Services, Los Angeles, CA; Sina Ma, Chinatown Service Ctr, Los Angeles, CA; Carol Lee Thorpe, Independent Living Systems, Los Angeles, CA; Carmen Reyes, Catherine Sarkisian, UCLA, Los Angeles, CA

Abstract Body: INTRODUCTION: Stroke disproportionately affects minority seniors and up to 30% of ischemic strokes in the US can be credited to physical inactivity.
AIM: To test a culturally-tailored intervention to reduce stroke risk in hypertensive African-American, Latino, Chinese, and Korean seniors by increasing physical activity.
HYPOTHESIS: The intervention will yield meaningful changes in physical activity and stroke risk knowledge with feasibility to sustain and scale within the aging services network.
DESIGN: Using principles of community-based participatory research, hypertensive seniors are enrolled at senior centers, complete baseline data collection, and are randomized into the intervention "Worth the Walk" immediately (N=120) or in 90 days upon completion of all data collection (N=120, control). Blinded RAs collect data from both groups 1 and 3-months post baseline.
INTERVENTION: Trained case managers run hour-long interactive group discussion sessions twice weekly for four consecutive weeks.
OUTCOMES: Primary outcomes are mean steps/day over 7 days as measured by a pedometer, stroke knowledge, and self-efficacy for reducing stroke risk. Secondary outcomes are selected biomarkers of health. A process evaluation assesses barriers/facilitators to integrating Worth the Walk into the aging services network and estimates costs to sustain and scale it.
ANALYSIS: Standard analytic methods for randomized controlled trials will be conducted using intention to treat.
CONCLUSIONS: Worth the Walk could serve as a primary stroke prevention model for ethnic communities across the US if it reveals superior improvements in walking, stroke knowledge, and is found to be sustainable and scalable.
STATUS AND REGISTRATION: N = 152 enrolled: African-American (n=58), Latino (n=64), Korean (n=30), Chinese (pending). Data collection ongoing and ends in December 2016; results available in 2017.Culturally Tailoring a Stroke Intervention in Community Senior Centers (SPIRP), sponsored by UCLA, registration ID: NCT02181062, PI: Catherine Sarkisian.

Author Disclosure Block: D. Araiza: None. **I. Kwon:** None. **B. Mittman:** None. **H. Liu:** None. **S. Song:** None. **L. Trejo:** None. **P. Willis:** None. **J. Kotick:** None. **S. Ma:** None. **C. Thorpe:** None. **C. Reyes:** None. **C. Sarkisian:** None.

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Presentation Number: CTP35

Publishing Title: The Surpass™ Intracranial Aneurysm Embolization System Pivotal Trial to Treat Large or Giant Wide Neck Aneurysms (SCENT Trial)

Author Block: Mark Bain, Gabor Toth, Cleveland Clinic, Cleveland, OH; Philip Meyers, Coulmbia Univ, New York, NY; Ricardo Hanel, Lyerly Neurosurgery, Jacksonville, FL

Abstract Body: Background: Large and giant intracranial aneurysms remain challenging lesions for endovascular treatment. The Surpass™ Flow Diverter (Stryker Neurovascular, Fremont, CA) is a braided endoprosthesis that was designed to treat intracranial aneurysms that are not amenable to surgical or current standard endovascular treatment.
Methods: The SCENT trial is an international multi-center, prospective, non-randomized trial comparing safety and efficacy outcomes of the Surpass Flow Diverter to a historical control used in the treatment of large or giant wide neck intracranial aneurysms. Eligible subjects are required to be 19 to 80 years of age, have a single targeted intracranial aneurysm that is located in the internal carotid artery (ICA) distribution up to the terminus with a neck ≥4 mm or no discernible neck and an aneurysm size ≥10 mm. (including saccular, fusiform and dissecting configuration). The primary safety endpoint is the percent of subjects experiencing neurologic death or major ipsilateral stroke through 12 months. The primary effectiveness endpoint is the percent of subjects with 100% occlusion (Raymond Class 1) without clinically significant stenosis (defined as < 50% stenosis) of the parent artery and without any subsequent treatment of the target aneurysm at 12 months.
Results: Twenty-six (26) sites are currently enrolling and treating subjects (25 in the US, 1 in Europe). A total of 178 patients have undergone treatment, with 211 treated (33 as roll-in subjects; 178 as protocol evaluable subjects).
Conclusion: Study enrollment completion is expected in Q4 2015.

Author Disclosure Block: M. Bain: Consultant/Advisory Board; Modest; Stryker Neurovascular Consultant. **G. Toth:** None. **P. Meyers:** None. **R. Hanel:** Ownership Interest; Modest; Shareholder in Blockade. Consultant/Advisory Board; Modest; Consultant to: Stryker Neurovascular, Covidien, Codman Neuro, and MicroVention; member of Scientific Advisory Board to Medina Medical.

Presentation Number: CTP36

Publishing Title: Acute Video-oculography for Vertigo in Emergency Rooms for Rapid Triage

Author Block: David E Newman-Toker, **Vahid Eslami**, Johns Hopkins Univ Sch of Med, Baltimore, MD; Jorge C Kattah, Univ of Illinois. Coll of Med. Peoria, Illinois, Peoria, IL; Kevin A Kerber, Univ of Michigan Health System, Ann Arbor, Mich, Ann Arbor, MI; Ari Blitz, John P Carey, Daniel R Gold, Daniel A Herzka, Johns Hopkins Univ Sch of Med, Baltimore, MD; William J Meurer, Univ of Michigan Health System, Ann Arbor, Mich, Ann Arbor, MI; William V Padula, Johns Hopkins Bloomberg Sch of Public Health, Guilford, CT; Richard E Rothman, Richard E Thompson, Zheyu Wang, David S Zee, Johns Hopkins Univ Sch of Med, Baltimore, MD; Jennifer Fowler, Univ of Michigan Health System, Ann Arbor, Michigan, Ann Arbor, MI; Cynthia I Guede, Univ of Illinois. Coll of Med. Peoria, Illinois, Peoria, IL; John W Hafner, OSF Saint Francis Medical Ctr, Peoria, IL; Daniel McGillicuddy, St. Joseph Mercy Ann Arbor, Ann Arbor, MI; Hardin Pantle, Bayview Hosp, Johns Hopkins Univ Sch of Med,, Baltimore, MD; Joshua Betz, Rachel Dlugash, Jennifer Houser, Maningbe Keita, Karen Lane, Vanessa A Llewellyn, Ryan Majkowski, Steven Mayo, Nichol McBee, Andrew Mould, Daniel F Hanley, Johns Hopkins Univ Sch of Med, Baltimore, MD

Abstract Body: Background
Vertigo and dizziness lead to 4.4 million US emergency department (ED) visits annually at a cost of ~$10 billion. Of these, ~3.5% (130,000-220,000) are due to stroke. Roughly 35% of strokes are missed initially, resulting in treatment delays and patient harms. In addition, most of the ~1 million patients with peripheral vestibular causes are over-tested, misdiagnosed, and undertreated. Accurate and efficient diagnosis will save lives and reduce costs through prompt and appropriate treatments.
Objective
To compare the impact of a novel, video-oculography (VOG)-guided diagnostic care pathway relative to standard diagnostic care on diagnostic accuracy, resource utilization, costs, treatments applied, and short-term health outcomes.
Design
This study is a multicenter (3-site), patient-level randomized, parallel design (1:1 ratio) Phase II clinical trial of VOG-guided vs. standard care to improve diagnosis and initial management for patients with vertigo or dizziness suspected to be of vestibular cause. We will recruit 226 adult ED patients with a chief symptom of new (< 7 days) vertigo or dizziness and at least one pathologic vestibular eye movement abnormality on pre-randomization VOG testing. We will perform VOG testing on all subjects using a portable device that measures eye movements quantitatively at the bedside. Patients will then be randomized to VOG-guided vs. standard care. In the VOG arm, patients will be diagnosed and treated according to a standard, predefined protocol guided by VOG results using automated, evidence-based decision rules. All patients will undergo follow-up testing at one week that includes 3-Tesla MRI with contrast, laboratory-based vestibular function tests, and a a neuro-otology exam. We will follow patients for 1 month for revisits and readmissions, reviewing records for stroke or related events. The diagnostic reference standard is a final diagnosis adjudicated by a masked, multidisciplinary panel of experts from neuro-otology, vascular neurology, neuroradiology, and emergency medicine.
Conclusion

We will evaluate the accuracy, safety, and efficiency of the VOG-guided rapid triage to differentiate peripheral from central vestibular disorders in ED patients presenting acute vertigo or dizziness.

Author Disclosure Block: **D.E. Newman-Toker:** Other Research Support; Modest; GNotometrics has loaned devices for use in the AVERT clincal trial. **V. Eslami:** None. **J.C. Kattah:** Other Research Support; Modest; GNotometrics has loaned devices for use in the AVERT clincal trial. **K.A. Kerber:** Other Research Support; Modest; GNotometrics has loaned devices for use in the AVERT clincal trial. **A. Blitz:** None. **J.P. Carey:** None. **D.R. Gold:** None. **D.A. Herzka:** None. **W.J. Meurer:** None. **W.V. Padula:** None. **R.E. Rothman:** None. **R.E. Thompson:** None. **Z. Wang:** None. **D.S. Zee:** None. **J. Fowler:** None. **C.I. Guede:** None. **J.W. Hafner:** None. **D. McGillicuddy:** None. **H. Pantle:** None. **J. Betz:** None. **R. Dlugash:** None. **J. Houser:** None. **M. Keita:** None. **K. Lane:** None. **V.A. Llewellyn:** None. **R. Majkowski:** None. **S. Mayo:** None. **N. McBee:** None. **A. Mould:** None. **D.F. Hanley:** None.

Presentation Number: CTP37

Publishing Title: Electronic Decision Support for Improvement of Contemporary Therapy for Stroke Prevention (EDICTS)

Author Block: Seemant Chaturvedi, Univ of Miami Miller Sch of Med, Miami, FL; Shyam Prabhakaran, Northwestern Univ, Chicago, IL; Adam Kelly, Univ of Rochester, Rochester, NY; Amer Malik, Univ of Miami Miller Sch of Med, Miami, FL; Lilly Lee, Jackson Memorial Health System, Miami, FL; Gustavo Saposnik, Univ of Toronto, Toronto, ON, Canada

Abstract Body: BACKGROUND: Despite the publication of numerous guidelines, oral anticoagulation (OAC) treatment for patients with atrial fibrillation (AF) appears to have hit a ceiling. In practice, only about 60% of AF patients without contraindications actually receive OAC therapy.
Embedding an Electronic Alert (EA) in the electronic medical record can potentially improve the rate of guideline concordant care for patients with AF. METHODS: We shall concentrate on patients discharged from the Emergency Department (ED) and patients admitted to the hospital with an AF diagnosis. An EA will be triggered for these patients and if the patient is not already on OAC treatment, the CHADS-VASC score will be calculated and a treatment recommendation provided.
DESIGN: We plan a three center study (two active intervention and one control site). Each site will recruit 120 patients over six months (total sample size 360).
HYPOTHESES: Specific aims are: 1) To demonstrate that electronic decision support will improve the rate of OAC utilization at the active intervention sites 2) To assess the use of OAC in patients >80 years and in women. The primary outcome is OAC utilization at a mean follow-up of six months after ED discharge or hospital admission. The hypothesis is that active intervention sites will have a 15% absolute increase in OAC use compared to usual care.
CONCLUSION: Electronic decision support has proven useful in a variety of settings, including guiding DVT prophylaxis. We aim to demonstrate that computerized decision support can also improve the quality of AF stroke prophylaxis.

Author Disclosure Block: **S. Chaturvedi:** Research Grant; Significant; Research support from Boehringer Ingelheim. **S. Prabhakaran:** None. **A. Kelly:** None. **A. Malik:** None. **L. Lee:** None. **G. Saposnik:** None.

Presentation Number: CTP38

Publishing Title: Insights on Selected Procoagulation Markers and Outcomes in Stroke Trials (I-SPOT)

Author Block: Nina T Gentile, A. Koneti Rao, **Hannah Reimer**, Temple Univ, Philadelphia, PA; Askiel Bruno, Georgia Regents Univ, Augusta, GA; Viswanathan Ramakrishnan, Medical Univ of South Carolina, Charleston, SC; William Barsan, Univ of Michigan, Detroit, MI

Abstract Body: Background Markers of blood coagulation are elevated in hyperglycemia and in acute ischemic stroke (AIS). The effect of blood glucose control after AIS on levels of markers of tissue factor pathway of blood coagulation and their relationship to stroke outcomes is unknown.
Objectives
To determine the relationships between levels of blood coagulation markers and hyperglycemia control and functional neurological outcome in Stroke Hyperglycemia Insulin Network Effort (SHINE) treatment and control patients.
Design
The I-SPOT Trial is designed to accompany SHINE clinical trial. SHINE is a multicenter, randomized, controlled trial with 2 treatment arms: glucose control (80 - 130 mg/dL) using insulin infusion versus standard sliding scale insulin with target glucose <180 mg/dL.
Protocol Modification
We plan to modify the exclusion criteria to include subjects who have received tissue plasminogen activator (tPA)
Population
SHINE enrolled subjects (adult AIS patients with hyperglycemia) who have not received anticoagulants, have no severe liver disease nor hypercoaguable disorders are eligible for I-SPOT.
Sample Size
315 Subjects will be enrolled in the I-SPOT trial
Intervention
Blood coagulation marker levels will be measured before and at 48 hours after the start of glucose control treatment.
Outcome Measures
At 90 days participants have modified Rankin Scale (mRS) and Quesionnaire for Verifying Stroke Free Symptoms (QVSFS) assessments performed.
Statistical Analysis
Baseline and 48-hour changes in biomarkers levels will be compared between SHINE treatment groups and between groups by clinical outcome. The baseline NIHSS stroke severity adjusted difference in favorable outcome between the treatment groups will be used to assess the relationships between markers of blood coagulation and clinical outcome and to determine if hyperglycemia control modulates the relationship between these biomarkers and clinical outcome in patients with hyperglycemia after stroke.
Results
Complete samples have been drawn from 79 of the 89 subjects.

Trial Status
Enrollment is ongoing at 43 of the approximately 50 SHINE sites. As of October 30, 2015, 89 subjects have been enrolled.

Author Disclosure Block: **N.T. Gentile:** Research Grant; Significant; NIH-NINDS 1U01NS079077-01A1. **A.K. Rao:** Research Grant; Significant; NIH-NINDS 1U01NS079077-01A1. **H. Reimer:** Research Grant; Significant; NIH-NINDS 1U01NS079077-01A1. **A. Bruno:** None. **V. Ramakrishnan:** Research Grant; Significant; NIH-NINDS 1U01NS079077-01A1. **W. Barsan:** None.

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Presentation Number: CTP39

Publishing Title: Platelet-Oriented Inhibition in New TIA and Minor Ischemic Stroke (POINT) Trial

Author Block: Clay Johnston, Univ of Texas Austin, Austin, TX; JDonald Easton, Anthony Kim, UCSF, San Francisco, CA; Jordan Elm, Medical Univ of South Carolina, Charleston, SC; **Mary Farrant**, UCSF, San Francisco, CA

Abstract Body: The Platelet-Oriented Inhibition in New TIA and minor ischemic stroke (POINT) Trial, is a prospective, randomized, double-blind, multi-center trial with the primary null hypothesis that, in patients with TIA or minor ischemic stroke treated with aspirin 50-325 mg/day, there is no difference in survival free of ischemic stroke, myocardial infarction, and ischemic vascular death at 90 days in those treated with clopidogrel (600 mg loading dose then 75 mg/day) compared to placebo, when therapy is initiated within 12 hours of the time last known free of new ischemic symptoms.
Subjects are 18 years of age or older with high-risk TIA (defined as an ABCD2 score > 4) or minor ischemic stroke (an NIHSS < 3); each subject is followed for 90 days from randomization. A total of 5,840 patients will be recruited and the trial will be completed in 7 years. The first subject was enrolled on May 28, 2010. International sites joined the POINT trial in August of 2013.

Author Disclosure Block: **C. Johnston:** Research Grant; Modest; NIH/NINDS. **J. Easton:** Research Grant; Significant; NIH/NINDS. **A. Kim:** Research Grant; Modest; NIH/NINDS. **J. Elm:** Research Grant; Modest; NIH/NINDS. **M. Farrant:** Research Grant; Significant; NIH/NINDS.

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Presentation Number: CTP40

Publishing Title: Periodontal Treatment to Eliminate Minority Inequality and Rural Disparities in Stroke (PREMIERS)

Author Block: Souvik Sen, Lauren C Dennis, Erin M Suttman, USC Sch of Med, Columbia, SC; Saundra Glover, James Hardin, Anwar T Merchant, Brian Chen, Univ of South Carolina, Columbia, SC; David Hicklin, James Curtis, Cynthia Nichols, Palmetto Health Dental Ctr, Columbia, SC; Steven Offenbacher, Carol Culver, Sherrill T Phillips, UNC Sch of Dentistry, Chapel Hill, NC; William J Powers, David Y Huang, UNC Sch of Med, Chapel Hill, NC; Sonia Davis, Sheila Burgard, UNC Collaborative Studies Coordinating Ctr, Chapel Hill, NC

Abstract Body: PeRiodontal treatment to Eliminate Minority InEquality and Rural disparities in Stroke (PREMIERS) is a two center, phase III, randomized, controlled trial to test the hypothesis that periodontal treatment reduces the risk of recurrent vascular events secondary to ischemic stroke and TIA.

We will randomize patients ≥18 years of age with a non-disabling stroke or TIA within the last 90 days and periodontal disease (≥ 5 teeth with ≥ 2 interproximal sites with ≥ 4 mm of clinical attachment loss and at least two sites with a probing pocket depth of 5+ mm) for treatment. These patients will be randomized to control periodontal treatment or intensive periodontal treatment.

Adaptive randomization technique will ensure treatment groups to be balanced in proportions of confounders (stroke severity, race, socioeconomic status, and stroke risk score).

The study will use composite vascular events (ischemic stroke, myocardial infarction, and cardiovascular death) as primary outcome events. The study will measure progression of carotid atherosclerosis, blood pressure, high sensitivity C-reactive protein, hemoglobin A1C, and fasting lipid profiles as secondary outcomes at baseline and 1 year follow up visit. Additional data will include cost-effectiveness, medical compliance, cognitive and sleep apnea.

We will enroll 400 subjects, assuming a ~10% attrition rate, to get a final sample size = 350, alpha = 0.050, overall probability of positive outcome = 0.450, of (A) or (B) with all covariates = 0.400 [(A) Percent of binary covariate equal to 1 (treatment) = 50.0%, (B) Percent of binary covariate equal to 1 (race-by-treatment) = 25.0%]. We will have an 80% power in logistic regression to declare as significant parameter associated with an estimated odds ratio of (A) 0.442 and (B) 0.381.

An interim analysis to detect early efficacy will be conducted after completion of 3 years of the study using an O'Brien-Fleming boundary of $p<0.005$. A DSMB will monitor safety every 3-6 months. In addition, we will conduct annual formal interim evaluations for study suspension due to excessive cardiovascular death related to treatment using a 1-sided Pocock boundary of $p< 0.008$.

The study spans over a period of five years; enrollment will start in November 2015, lasting for an estimated three years.

Author Disclosure Block: S. Sen: None. **L.C. Dennis:** None. **E.M. Suttman:** None. **S. Glover:** None. **J. Hardin:** None. **A.T. Merchant:** None. **B. Chen:** None. **D. Hicklin:** None. **J. Curtis:** None. **C. Nichols:**

None. **S. Offenbacher:** None. **C. Culver:** None. **S.T. Phillips:** None. **W.J. Powers:** None. **D.Y. Huang:** None. **S. Davis:** None. **S. Burgard:** None.

Presentation Number: CTP41

Publishing Title: Eric Acute Stroke Recanalisation

Author Block: Jens Fiehler, Univ Medical Ctr Hamburg Eppendorf, Hamburg, Germany; Nils Forkert, Hotchkiss Brain Institure, Calgary, AB, Canada; Jan-Hendrik Buhk, Andre Kemmling, Goetz Thomalla, Univ Medical Ctr Hamburg Eppendorf, Hamburg, Germany

Abstract Body: Objectives: Recent studies proved the clinical effectiveness of second generation mechanical thrombectomy (MT) devices in combination intravenous tPA. Next generation MT devices in combination with local thrombus aspiration and intravenous tPA appear to safe and effective for recanalization. Their efficacy on the brain tissue level or on clinical outcome is unproven.
Methods: ERic Acute StrokE Recanalisation (ERASER) is an investigator-initiated international multi-centre single-arm study evaluating the effect of the ERIC™ device in combination with SOFIA™ Distal Access Catheter (both Microvention, Tustin, CA, USA) on tissue outcome and on clinical outcome (NCT02534701). Key inclusion criteria are usage of ERIC in combination with SOFIA as first device, acute ischemic stroke with NIH-SS score of 8-25, confirmed M1-occlusion, perfusion imaging <4.5h after symptom onset completed and groin puncture <6h. Sixty patients meeting all in- and exclusion criteria will be enrolled in the predictive analytics cohort (from up to 12 centers in Germany and Switzerland). All other patients will be monitored in a supplementary study arm. The primary effectiveness endpoint is the volume of saved tissue (VOST) as difference of the brain volume with an infarct risk of >50%, based on a prediction- algorithm trained in a cohort treated with IV tPA (VIV) and the actual infarct volume (VMT) in the ERASER cohort (VOST=VIV-VMT). Angiographic images will be assessed by the local centers and additionally by an independent core lab.
Results: The first patient has been included in May 2015. At time of this writing, 15 patients are enrolled in three study centers. Eight more centers in Germany and Switzerland are in the process of initiation. There are no indications for increased procedural risk and the recanalization rate suggests no futility.
Discussion: Evaluating the efficacy of neurointerventional procedures is a considerable challenge. ERASER is the first neurovascular study using advanced predictive analytics for the primary endpoint for testing of a new endovascular device. Such information could increase future patient safety by earlier detection of missing efficacy signals or accelerate the patient's access to new technology.

Author Disclosure Block: J. Fiehler: Research Grant; Significant; Microvention Inc., Tustin, CA, USA. Speakers' Bureau; Modest; Codman, Microvention, Penumbra. Consultant/Advisory Board; Modest; Boehringer, Codman. **N. Forkert:** None. **J. Buhk:** Speakers' Bureau; Modest; Codman, Microvention. Consultant/Advisory Board; Modest; Codman, Microvention. **A. Kemmling:** None. **G. Thomalla:** Speakers' Bureau; Modest; Boehringer.

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Presentation Number: CTP42

Publishing Title: BASE Biomarkers of Acute Stroke Etiology NCT02014896

Author Block: Jeffrey June, Ischemia Care, Cincinnati, OH

Abstract Body: Background
The cause of ischemic stroke (IS) remains uncertain (or cryptogenic) in up to 40% of cases. Undetected atrial fibrillation (AF) during evaluation for cause of IS is a significant risk factor for recurrent events. A blood test based upon RNA expression could be used to stratify IS patients by cause and reduce the number of cryptogenic events to ensure appropriate treatment regimens are adopted to prevent recurrence.
Objectives
Clinically validate a blood test to:
1. Differentiate between clinically diagnosed cardioembolic and large artery atherosclerotic IS.
2. Categorize cryptogenic strokes, as cardioembolic or large artery atherosclerotic when standard clinical testing cannot determine the cause.
3. Further sub classify cardioembolic strokes into those caused by AF and those not caused by AF.
Design
600 subject observational prospective study. Serial samples drawn within 8hr onset, 24h and 48h. Samples processed on microarrays at the Ischemia Care laboratory.
Study Population
1. IS patients
2. Normal controls matched with patients for age, race, gender, smoking, plus vascular risk factors
Inclusion Criteria
• Patients >18 years of age
• Symptoms suggestive of IS
• 8h of symptom onset or last known normal time
• CT/ MRI ruling out other pathology
Exclusion Criteria
• Central nervous system infection (30 day)
• Head trauma, stroke or intracranial hemorrhage (30 day)
• Cancer
• Autoimmune or infectious diseases
Outcome
Clinically validated algorithm.
Status
Enrolling at 18 stroke centers and ~ 340 subjects enrolled through Oct 2015

Author Disclosure Block: J. June: None.

Presentation Number: CTP43

Publishing Title: Critical Periods After Stroke Study (CPASS): A Phase II Trial

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Abstract Body: Background: Better treatment of stroke, whether to reduce impairment or target the goals and preferences of individuals, can enable independence and increase participation. We are investigating the optimal time after stroke for intensive upper extremity motor training.
There is evidence for timing effects in rehabilitation; motor training delivered at certain times may be more effective. It is hypothesized that the periods of greatest responsiveness after a stroke are analogous to the sensitive periods in normal human development. We expect that individuals receiving early intensive motor training will show greater upper extremity motor improvement measured at one year post stroke compared to individuals receiving therapy at later time points.
Methods and Analysis: 64 participants will be adaptively randomized to receive an additional bolus of 20 hours of upper extremity therapy either within 30 days post-stroke, 2-3 months post-stroke, 6-9 months post-stroke, or to a control group. The primary outcome is the Action Research Arm Test at one year. Blood will be drawn at up to 3 time points for biomarker studies.
Results: We have enrolled two run-in subjects and randomized twenty-two participants to date; the study will be completed in 3 years. Results from this study will help to plan a Phase III clinical trial.
Conclusion: If sensitive periods exist in rehabilitation and can be identified after stroke, then current resources can be better targeted to promote recovery. Inclusion of biomarker determination opens up the possibility of understanding the biological mechanisms of recovery and supports future drug development.

Author Disclosure Block: **A.W. Dromerick**, NextStim NICHE Trial DSMB, Modest,Consultant/Advisory Board; **D.F. Edwards**, None; **M.A. Edwardson**, None; **M.L. Giannetti**, None; **J. Barth**, None; **K.P. Brady**, None; **C.P. Wilson**, None; **E. Chan**, None; **S. Geed**, None; **M.T. Tan**, None; **M.S. Fiandaca**, Co-inventor on provisional patent applications that have been filed by Georgetown University and the University of Rochester related to specific biomarker technologies, Modest,Other; **H.J. Federoff**, Co-inventor on provisional patent applications that have been filed by Georgetown University and the University of Rochester related to specific biomarker technologies, Modest,Other; **E.L. Newport**, None.

Presentation Number: CTP44

Publishing Title: Community Engagement for Early Recognition and Immediate Action in Stroke (CEERIAS) Study

Author Block: Shyam Prabhakaran, Northwestern Univ, Feinberg Sch of Med, Chicago, IL; Knitasha Washington, Governors State Univ, University Park, IL; Erin Wymore, Northwestern Univ, Feinberg Sch of Med, Chicago, IL; Peggy Jones, Illinois Critical Access Hosp Network, Normal, IL; Amy Eisenstein, Namratha Kandula, Christopher T Richards, Jen Brown, Northwestern Univ, Feinberg Sch of Med, Chicago, IL; Sarah Song, Rush Univ, Chicago, IL; Maryann Mason, Soyang Kwon, Northwestern Univ, Feinberg Sch of Med, Chicago, IL; Neelum Aggarwal, Rush Univ, Chicago, IL

Abstract Body: Background: Stroke is a leading cause of adult disability in the US, with disproportionately higher risk and worse outcomes among minorities. Early action is a critical first step to timely access to reperfusion therapy.
Appropriate action after symptom recognition (i.e. call 911) may be influenced by misperceptions, fears, cultural mores, financial strains, and institutional barriers. Patient and community engagement may be vital to understanding these barriers and crafting culturally appropriate interventions that promote stroke awareness and early action. Preliminary data estimate that only 45% of stroke patients in Chicago use emergency medical services (EMS) and 28% arrive to the hospital within 3 hours.
Objective: 1) To examine barriers and facilitators to calling 911 after stroke onset in neighborhoods surrounding 2 hospitals on the south side of Chicago; 2) To implement a culturally-adapted stroke awareness and action program and monitor its penetration and adoption in the targeted neighborhoods; and 3) To assess change in early hospital arrival and EMS use at the 2 targeted hospitals before and after the community intervention.
Design: Community-partnered interventional study.
Study population: Residents living in the south side of Chicago surrounding 2 primary stroke center hospitals will be targeted for a community-partnered stroke awareness and action educational campaign.
Intervention: A culturally-adapted stroke awareness and action program will be delivered by trained Stroke Promoters in the targeted neighborhoods. Community Stroke Promoters will be trained on 1) the benefits of early recognition and EMS utilization for stroke, 2) culturally-adapted solutions to current barriers, and 3) cues to aid in stroke recognition and immediate action.
Outcome measure: The co-primary outcome measures are 1) hospital arrival within 3 hours of symptom onset and 2) arrival by EMS.
Analysis: We will use an interrupted time-series analysis of EMS use and early hospital arrival among stroke patients before and after our intervention at the 2 targeted hospitals.
Status: Intervention implementation ongoing.

Author Disclosure Block: **S. Prabhakaran**, NINDS; PCORI, Significant,Research Grant; **K. Washington**, None; **E. Wymore**, None; **P. Jones**, None; **A. Eisenstein**, None; **N. Kandula**, None; **C.T. Richards**, None; **J. Brown**, None; **S. Song**, None; **M. Mason**, None; **S. Kwon**, None; **N. Aggarwal**, None.

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Presentation Number: CTP45

Publishing Title: Comparative Effectiveness of Treatment Options Using Propensity Score Methods in Cervical Artery Dissection (COMPASS)

Author Block: Neil Patel, Nikil Swamy, Ravish Kothari, Lauren C Dennis, Erin M Suttman, Souvik Sen, USC Sch of Med, Columbia, SC

Abstract Body: Cervical artery dissection (CAD), is a rare condition (estimated incidence in the US of 15,000/year), considered to be one of the leading causes of stroke in the young and middle-aged population. Observational studies overcome limitations of randomized clinical trials in being less costly, expedient, and ethically preferable when alternative effective treatments with equipoise exist. Comparative Effectiveness Of Treatment Options Using Propensity Score Methods In Cervical Artery Dissection (COMPASS) is a resident-driven prospective registry to test the comparative effectiveness of two presently employed treatment arms in patients with cervical artery dissection (CAD) antiplatelet therapy versus oral anticoagulation therapy.
We will enroll patients at least 18 years or older with extracranial carotid or vertebral artery dissection with symptom onset within the last 90 days of evaluation who will be confirmed by radiological evidence of CAD. Physician-chosen treatment of anticoagulation, antiplatelet therapy, and/or no treatment in addition to demographic data will be reported at the time of enrollment.
Aided by web-based data capture tools, these patients will be followed for 12 months, with follow up telephone interviews occurring at the 3, 6 and 12 month marks. Outcome measures related to death, stroke/TIA, all- cause readmission, bleeding readmission, and “home time” (days spent alive and at home) will be assessed using standardized methods. Propensity score analysis will be used to adjust for covariates that confound the association between treatment and outcome events, to yield levels of evidence equivalent to that obtained in randomized controlled trials.
Sample size is based on preliminary data collected by CADISS (Cervical Artery Dissection In Stroke Study-University of Cambridge) per-protocol endpoint of Stroke, death or major bleeding: 3/101 (antiplatelet arm) v 2/96 (anticoagulant arm) ~10,000 subjects are required to achieve a power of 80% and significance level of 0.05. 24 patients have been recruited in one center since January 2015. Recruitment of additional 100 centers for an enrollment period of three years will be required to achieve the enrollment goal.

Author Disclosure Block: N. Patel: None. **N. Swamy:** None. **R. Kothari:** None. **L.C. Dennis:** None. **E.M. Suttman:** None. **S. Sen:** None.

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Presentation Number: CTP46

Publishing Title: Mechanisms of early Recurrence in Intracranial Atherosclerotic Disease (MyRIAD)

Author Block: David S Liebeskind, UCLA, Los Angeles, CA; Shyam Prabhakaran, Northwestern Univ, Chicago, CA; Iszet Campo-Bustillo, Univ of Miami, Miami, FL; Qi Long, Emory Univ, Atlanta, GA; Edward Feldmann, Baystate Medical Ctr, Springfield, MA; Jose G Romano, Univ of Miami, Miami, FL; for the MyRIAD Investigators

Abstract Body: Background: Intracranial atherosclerotic disease (IAD) causes up to 10% of strokes in the US and may be the most important cause of stroke worldwide. The risk of recurrent stroke is 12% at 1 year despite aggressive medical management. The mechanisms for recurrent stroke remain unclear. Progressive arterial narrowing, plaque instability (thrombo-embolism), and exhausted vasomotor reactivity with impaired collateral flow are potential mechanisms that may elevate stroke risk.
Objective: To elucidate the mechanisms that underlie ischemic stroke in patients with symptomatic IAD and determine high-risk predictors of recurrent stroke.
Design: Prospective, multi-center, longitudinal observational study.
Study population: 175 patients with stroke or TIA within 21 days caused by IAD with stenosis 70-99%.
Intervention: Baseline TCD with emboli detection and vasomotor reactivity, quantitative magnetic resonance angiography and MR perfusion-weighted imaging within 21 days of the index stroke or TIA; 30-day MRI with fluid attenuation inversion recovery and diffusion-weighted imaging.
Outcome measure: Primary outcome measure: time to ischemic stroke in the territory of the stenotic artery within 1 year. Secondary outcome measures: new infarcts on DWI MRI within 30 days and recurrent TIAs in the territory of the stenotic artery.
Analysis: Log-rank tests will be used to test the relationship between the time to ischemic stroke in the territory and each of the dichotomized imaging measurement variables. Cox proportional hazards regression will be used to estimate hazard ratios for each imaging variable, adjusting for other potential risk factors, and test interactions between imaging biomarkers.
Status: Ten recruiting sites in the US; enrollment ongoing.
Sponsor: NIH/NINDS
Website: http://clinicaltrials.gov/ct2/show/NCT02121028

Author Disclosure Block: D.S. Liebeskind: None. **S. Prabhakaran:** None. **I. Campo-Bustillo:** None. **Q. Long:** None. **E. Feldmann:** None. **J.G. Romano:** None.

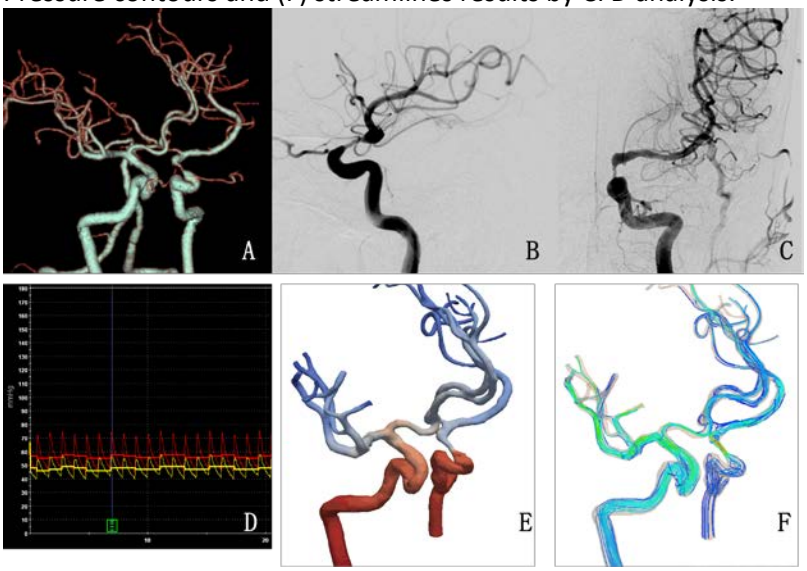
Presentation Number: CTP47

Publishing Title: Noninvasive Assessment of Fractional Flow Using Supercomputing Techniques for Patients With Symptomatic Intracranial Stenosis

Author Block: Yuehua Pu, Beijing Tiantan Hosp of Capital Medical Univ, Beijing, China; Jia Liu, Shenzhen Insts of Advanced Technology, Chinese Acad of Sciences, Shenzhen, China; Liping Liu, Zhongrong Miao, Yilong Wang, Xin Liu, Baixue Jia, Beijing Tiantan Hosp of Capital Medical Univ, Beijing, China; Xiaochuan Cai, Shenzhen Insts of Advanced Technology, Chinese Acad of Sciences, Shenzhen, China; Yongjun Wang, Beijing Tiantan Hosp of Capital Medical Univ, Beijing, China

Abstract Body: Background and purpose: Intracranial stenosis is an important etiology subtype of ischemic stroke in China. Fractional flow, denoted as ratio between the distal and proximal pressure of a stenosis, may be a functional parameter to identify high-risk intracranial lesions. The purpose of this study is to establish a method to evaluate fractional flow assessed by CT angiography using supercomputing technique.
Methods:We enroll patients had TIA or nondisabling stroke within 30 days before enrollment, attributed to intracranial stenosis of 70 to 99% verified by CTA or DSA. Pressures distal and proximal to the stenosis were measured by floating a pressure guidewire. CTA images were post processed for computational fluid dynamics (CFD) analysis using supercomputing techniques. A parallel domain decomposition algorithm was applied to simulate blood flows in the patient-specific artery. The incompressible Newtonian Navier-Stokes equations are employed to model the blood flow. Finally, we compare the data measured by pressure guidewire and CFD analysis for adjusting and evaluating the CFD method.
Results:We had finished 6 cases with both pressure guidewire measurement and CFD analysis before and after endovascular treatment. Consistency test showed the Cronbach' alpha was 0.932 between pressure guidewire and CFD measurement. The CFD model still has deviations in analysis lesion with good collateral circulation, and it needs to be further improved.
Conclusion:It is feasible and reliable to assessing fractional flow by pressure ratio on CTA using supercomputing technique for symptomatic intracranial stenosis.
Figure A 63y male, complained of paroxysmal right limbs numbness and weakness for 2 month. (A), (B), (C) CTA and DSA showed left ICA C6 severe stenosis, (D) yellow line showed the distal pressure of a stenosis, red line showed the proximal pressure measured by guidewire, pressure ratio was 0.83, (E)

Pressure contours and (F) streamlines results by CFD analysis.



Author Disclosure Block: **Y. Pu:** None. **J. Liu:** None. **L. Liu:** None. **Z. Miao:** None. **Y. Wang:** None. **X. Liu:** None. **B. Jia:** None. **X. Cai:** None. **Y. Wang:** None.

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Presentation Number: CTP48

Publishing Title: Prognostic Value of Endothelial Injury in Patients Undergoing Mechanical Thrombectomy for Emergent Large Vessel Occlusion: A Prospective Registry

Author Block: Lucas Elijovich, Adam Arthur, Daniel Hoit, Tommy Doss, Univ of Tennessee/Semmes-Murphey Clinic, Memphis, TN; David Morris, Mid South Imaging and Therapeutics, Memphis, TN; Andrey Belayev MD, Chris Nickele, Jay Vachhani, Univ of Tennessee/Semmes-Murphey Clinic, Memphis, TN; Edward Hord, Juan M Cardenas, Cirquest Labs, Memphis, TN; Lisa K Jennings, Univ of Tennessee Dept of Internal Med, Memphis, TN

Abstract Body: Rationale: The newest generation of mechanical thrombectomy (MT) devices have higher recanalization rates with improved outcomes in patients with acute ischemic stroke (AIS) due to emergent large vessel occlusion (ELVO). High rates of successful recanalization provide the first opportunity to routinely examine the emboli and plasma milieu surrounding ELVO. Endothelial injury (EI) during the procedure has been poorly characterized. We will evaluate the presence and degree of local clot and device-related EI, and investigate their contribution to the prognosis of AIS.
Methods/Outcomes: Single center prospective registry examining the gross pathologic and immunohistochemical characteristics of retrieved clots and local plasma from patients with ELVO. Twenty-five adult subjects undergoing MT will be eligible for enrollment in this first feasibility phase. Multicenter expansion with an n of 100 will be pursued.
The primary objective will be to explore the extent of EI in patients undergoing MT by advanced pathologic techniques.
Clinical outcomes will be assessed by NIHSS and Modified rankin scores at presentation, 7 days, and 30 days. Radiologic outcomes including infarct volume at presentation and discharge and presence of symptomatic intrancranial hemorrhage will be collected. Clinical variables will be collected including: patient baseline characteristics, clinical presentation, pre-treatment use of thrombolytics, and details of the MT procedure.
Study of markers of EI will include: 1. Quantification of the endothelial cell marker CD31 in thrombus material by staining techniques, 2. Quantification of CD31 expression from RNA extracted from the thrombus, 3. Use of immunohistochemistry, ELISA and reverse transcription quantitative PCR to detect other endothelial components, and 4. Measurement of endothelial-derived biomarkers, including soluable ICAM-1 and thrombomodulin in local plasma.
Multivariate regression techniques will be employed to examine the relationship of clinical variables and EI markers on outcome.
Trial Status: Recruiting as of September 2015. Four patients enrolled.

Author Disclosure Block: L. Elijovich: Research Grant; Modest; Baptist Memorial Healthcare, Siemens. Consultant/Advisory Board; Modest; Sequent, Microvention, Stryker, Codman J & J. **A. Arthur:** Other Research Support; Modest; Siemens. Consultant/Advisory Board; Modest; Sequent, Microvention, Covidien, Codman J & J. **D. Hoit:** Research Grant; Modest; Siemens. Consultant/Advisory Board; Modest;

Covidien, Medtronic, Sequent, Microvention. **T. Doss:** None. **D. Morris:** None. **A. Belayev:** None. **C. Nickele:** None. **J. Vachhani:** None. **E. Hord:** None. **J.M. Cardenas:** None. **L.K. Jennings:** None.

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Presentation Number: CTP49

Publishing Title: Change in Antiplatelet Therapy in Prevention of Secondary Stroke (CAPS2)

Author Block: Ravish Kothari, Neil Patel, Nikil Swamy, Lauren C Dennis, Erin M Suttman, Souvik Sen, USC Sch of Med, Columbia, SC

Abstract Body: Stroke is the leading cause of adult disability, death and healthcare cost in the United States. Approximately a third of patients are on daily aspirin regimen for indications of vascular prophylaxis. Clinicians have the options of maintaining the patients on Aspirin, or changing to Clopidogrel and combination Aspirin-Dipyridamole. Our goal is to test the comparative effectiveness, risks and safety of the three options in prevention of recurrent vascular events in stroke/TIA patients on Aspirin. Although, a randomized clinical trial (RCT) would be ideal to test comparative effectiveness, it may be cumbersome, and expensive.

Change in Antiplatelet Therapy in Prevention of Secondary Stoke (CAPS2) is a resident-driven prospective registry that will compare the effects of three different blood thinners in prevention of stroke, heart attack or death in stroke/TIA patients on Aspirin

We will enroll patients at least 18 years of age with a TIA with ABCD2 score of at least 4 or an imaging confirmed ischemic stroke within the last 30 days of evaluation. The patient has to be on daily Aspirin for ≥7 days prior to index stroke/TIA. Patient who presents with indications for oral anticoagulation or dual antiplatelet therapy will be excluded from the study.

Stroke/TIA patients will be enrolled and followed up for total twelve months, with telephone interviews occurring at six and twelve months mark. The primary study outcome of stroke, death and myocardial infarction will be assessed using the standardized methods. The project will use a cohort study design with web-based data capture. Observational data will be used in propensity score analysis to adjust for the baseline differences in treatment groups, to yield levels of evidence equivalent to that obtained by a RCT.

Sample size is based on preliminary data collected by CAPRIE (Clopidogrel versus Aspirin in Patients at Risk of Ischemic Events) and ESPS2 (Second European Stroke Prevention Study). Per-protocol endpoint of stroke, death, or vascular event: 5.83% (ASA arm) v. 5.32% (Clopidogrel arm) and per-protocol endpoint: 6.85%% (ASA arm) and 5.55% (ASA + Dipyridamole arm), respectively. Approximately 3,000 patients are required to achieve a power of 80% and significance level of <0.05. Over a 100 patients have been recruited.

Author Disclosure Block: R. Kothari: None. **N. Patel:** None. **N. Swamy:** None. **L.C. Dennis:** None. **E.M. Suttman:** None. **S. Sen:** None.

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Presentation Number: CTP50

Publishing Title: Memantine for Enhancement of Stroke Motor Recovery

Author Block: Alicia Bennett, K.C. Brennan, Edward DiBella, Ganesh Adluru, Lorie Richards, Jennifer J. Majersik, Univ of Utah, Salt Lake City, UT

Abstract Body: Background: Motor impairment is one of the leading cause of long-term morbidity following stroke. However, there is increasing evidence that plasticity is retained after stroke, offering the opportunity to enhance the recovery process. We found that memantine, a clinically-tolerable NMDA antagonist, improved sensory and motor outcome in a mouse model of stroke. Memantine is in common clinical use for Alzheimer Disease, which means it could be readily deployed for clinical use if warranted.
Hypothesis: Treatment with oral memantine for three months following an acute ischemic stroke will be feasible and be associated with an improvement in motor control as measured by the Fugl-Meyer score (FMS), with no greater serious adverse events. Secondarily, patients treated with memantine will have improvement in motor function as measured by the ten-meter walk, motor activity log (MAL), and stroke impact scale (SIS).
Methods: Adults with ischemic stroke are randomized into the study if they have upper extremity weakness warranting inpatient or outpatient rehabilitation, a FMS of ≤55, and are 3-8 days post-stroke. Participants are treated with memantine or placebo for a total of three months. Baseline, 1 month, and 3 month testing includes a FMS, ten meter walk, SIS, and MAL. We also have an optional substudy with an MRI scan at the same time intervals using a novel diffusion spectrum imaging technique.
Results: Three subjects have been enrolled to date. As recruitment has been slower than predicted, we recently expanded our enrollment criteria to include a larger age range and prior contralateral symptomatic strokes. We have had no difficulty with baseline testing, including scheduling and performing the MRI, and participants have tolerated baseline and follow-up testing without problems. All participants have come back for all follow-up testing, and there have been no serious adverse events. Medication adherence has been 100% via pill counts. We will continue to enroll until we meet our goal of 20 patients at which time outcomes and feasibility for a larger trial will be assessed.

Author Disclosure Block: A. Bennett: None. **K. Brennan:** Consultant/Advisory Board; Modest; Eli Lilly. **E. DiBella:** Research Grant; Modest; Siemens Medical Solutions. **G. Adluru:** None. **L. Richards:** Consultant/Advisory Board; Modest; Medbridge, Inc. **J.J. Majersik:** Research Grant; Significant; NIH grant 1U10NS086606.

Presentation Number: CTP51

Publishing Title: HEALS (Healthy Eating And Lifestyle after Stroke): A Pilot Trial of a Multidisciplinary Lifestyle Intervention Program for Stroke Survivors

Author Block: Valerie Hill, Rancho Los Amigos, Downey, CA

Abstract Body: Background: Adherence to a combination of healthy lifestyle practices - eating a healthy diet, exercising regularly, maintaining a normal body mass index (BMI), not smoking, and limiting alcohol - lowers risk of cardiac and cerebrovascular events, and reduces post-stroke mortality. Adherence to healthy lifestyle practices is poor among stroke survivors, particularly socioeconomically disadvantaged race/ethnic minorities.
Objective: To conduct a pilot test of an outpatient post-stroke lifestyle intervention in a safety-net healthcare system to 1) determine the feasibility of the program; 2) estimate and compare effect sizes for short-term changes in BMI, diet, and physical activity.
Design: Randomized control trial.
Population studied: One hundred adults (≥40 years of age) with ischemic stroke or TIA ≥90 days prior to study enrollment, systolic blood pressure >120 mm Hg, English- or Spanish-speaking,
Intervention: Six week lifestyle intervention with weekly 2-hour group sessions focusing on goal setting, health education, peer exchange, participation in healthy activities, overcoming potential obstacles, self-efficacy and self-management skills.
Outcome Measures: (1) maintaining a BMI of 18.5-24.9 kg/m2, (2) eating ≥ 5 servings fruits/vegetables per day, (3) exercising ≥12 times per month.
Analysis: Intention-to-treat analysis to determine whether persons randomized to intervention achieve better outcomes than persons randomized to usual care, at 6 months.

Author Disclosure Block: V. Hill: None.

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Presentation Number: CTP52

Publishing Title: Systematic Evaluation of Patients TREated with Neurothrombectomy Devices for AcuTe Ischemic Stroke (STRATIS) Registry

Author Block: Nils H Mueller-Kronast, Delray Medical Ctr/Tenet South Florida, Delray Beach, FL; Ali Aziz-Sultan, Brigham and Women's Hosp, Boston, MA; Michael T Froehler, Vanderbilt Univ Medical Ctr, Nashville, TN; **Reza Jahan**, UCLA Medical Ctr, Los Angeles, CA; Richard P Klucznik, Methodist Hosp, Houston, TX; Jeffrey L Saver, Univ of California Los Angeles, Los Angeles, CA; Osama O Zaidat, St. Vincent Mercy Hosp, Toledo, OH; Dileep R Yavagal, Univ of Miami/Jackson Memorial Hosp, Miami, FL

Abstract Body: Background and Objective: With the recently published results of the MR CLEAN, EXTEND IA, ESCAPE and SWIFT PRIME trials, treatment of large vessel occlusion with stent retrievers has become standard of care. Trial results greatly depended on their efficient triage and safe technique and limited data exists on how these results may be replicated in the community. The objective of this registry is to assess clinical outcomes associated with the use of Medtronic Neurovascular market-released neurothrombectomy devices intended to restore blood flow in patients experiencing acute ischemic stroke due to large intracranial vessel occlusion. **Design:** STRATIS is a prospective, multi-center, non-randomized, observational registry. The registry has three unique design aspects that distinguish it from other studies. The registry has independent core lab validation of imaging outcomes, and as a first, documents the impact of 6 forms of interventional techniques as well as type of anesthesia on the 90 day outcome. Moreover, the potential for large cohort of physiological perfusion images use for triage will be available from STRATIS Registry. Furthermore, it tracks the well-needed system of care data including transfer distances, referral patterns, times and location of stroke onset to ultimate interventional treatment. STRATIS will be the largest registry to date with this level of granular detail with intent to enroll 1000 patients within 8 hours from onset to groin puncture in 60 sites, 27 of which will be former SWIFT PRIME sites. **Outcome Measures:** Performance evaluation measures include time to revascularization and TICI flow at the end of the procedure. Safety evaluation measures include incidence of neurological events of interest, all-cause mortality, and incidence of device- and procedure-related serious adverse events up to 90 days post index procedure. Efficacy evaluation measures include NIHSS and mRS scores at hospital discharge and 90 days post index procedure. **Trial Status:** Actively recruiting. As of December 2015, 592 patients have been enrolled and 46 sites are participating. (NCT02239640)

Author Disclosure Block: N.H. Mueller-Kronast: Consultant/Advisory Board; Modest; Medtronic Neurovascular. **A. Aziz-Sultan:** Expert Witness; Modest; BMC. Consultant/Advisory Board; Modest; Medtronic Neurovascular. **M.T. Froehler:** Other Research Support; Modest; Site PI. Consultant/Advisory Board; Modest; Medtronic Neurovascular. **R. Jahan:** Research Grant; Significant; Medtronic Neurovascular. Consultant/Advisory Board; Significant; Medtronic Neurovascular. **R.P. Klucznik:** Speakers' Bureau; Modest; Medtronic Neurovascular. **J.L. Saver:** Consultant/Advisory Board; Modest; Stryker, Neuravia, Cognition Medical, Boehringer, Ingelheim. Consultant/Advisory Board; Significant; Medtronic. **O.O. Zaidat:** Consultant/Advisory Board; Modest; Medtronic Neurovascular. **D.R. Yavagal:**

Consultant/Advisory Board; Modest; Medtronic Neurovascular. Other; Modest; ESCAPE trial DSCMB member.