Randomized, Double Blind Trial of 6 Versus 12 Months Of Dual Antiplatelet Therapy After DES-Implantation (ISAR-SAFE)

Stefanie Schüpke (nee Schulz), Deutsches Herzzentrum München, Muenchen, Germany; Julinda Mehilli, Klinikum der Univ München, München, Germany; Karl-Ludwig Laugwitz, Klinikum rechts der Isar, Muenchen, Germany; Franz -Josef Neumann, Univs-Herzzentrum Freiburg – Bad Krozingen, Bad Krozingen, Germany; Jurrien M ten Berg, St. Antonius Hosp, Nieuwegein, Netherlands; Tom Adriaenssens, Univ Hosp Leuven, Leuven, Belgium; Yaling Han, Shenyang Northern Hosp, Shenyang, China; Barbara von Merzljak, Deutsches Herzzentrum München, Muenchen, Germany; Gert Richardt, Herzzentrum der Segeberger Kliniken Gruppe, Bad Segeberg, Germany; Melchior Seyfarth, Klaus Tiroch, Helios Klinik Wuppertal, Wuppertal, Germany; Tanja Morath, Deutsches Herzzentrum München, Muenchen, Germany; Michael Maeng, Aarhus Univ Hosp, Aarhus N, Denmark; Bernhard Zrenner, Krankenhaus Landshut-Achdorf, Landshut, Germany; Nonlag Rifatov, Deutsches Herzzentrum München, Muenchen, Germany; Claudius Jacobshagen, Univmedizin Goettingen, Goettingen, Germany; Harald Mudra, Klinikum Neuperlach, Muenchen, Germany; Eberhard Freiherr von Hodenberg, MediClin Herzzentrum Lahr/Baden, Lahr, Germany; Jochen Wöhrle, Univklinikum Ulm, Ulm, Germany; Sebastian Kufner, Christian Hengstenberg, Deutsches Herzzentrum München, Muenchen, Germany; Marcus Fischer, Univklinikum Regensburg, Regensburg, Germany; Martin Schmidt, Klinikum Bogenhausen, Muenchen, Germany; Franz Dotzer, Klinikum Garmisch-Partenkirchen, Garmisch-Partenkirchen, Germany; Tareq Ibrahim, Klinikum rechts der Isar, Muenchen, Germany; Peter Sick, Krankenhaus Barmherzige Brüder Regensburg, Regensburg, Germany; Christoph A Nienaber, Univsklinik Rostock, Rostock, Germany; Arnoud W J van 't Hof, Isala Klinieken Zwolle, Locatie Weeenlanden, Zwolle, Netherlands; Takeshi Kimura, Kyoto Univ Hosp, Kyoto, Japan; Bernhard Witzenbichler, Amper Kliniken Dachau, Dachau, Germany; Stephan Windecker, Inselspital, Univsspital Bern, Bern, Switzerland; Heribert Schunkert, Adnan Kastrati, Deutsches Herzzentrum München, Muenchen, Germany

Introduction:

The optimal duration of dual antiplatelet therapy (DAPT) after drug-eluting stent (DES) implantation is still a question of debate. Hypothesis:

We hypothesized that in patients with DES implantation a 6 month duration is not inferior to a 12 month duration of DAPT with aspirin and clopidogrel in terms of clinical outcomes.

Methods:
ISAR -SAFE is a randomized, double-blind, multicenter trial comparing 6 versus 12 months of clopidogrel therapy duration in patients with DES implantation. Patients were enrolled at 6 months after DES implantation and randomly assigned to either 6 further months of clopidogrel therapy or placebo. Based on sample size calculations the planned total number of patients was 6,000. A blinded overall analysis showed lower than expected event rates. This along with slow recruitment induced the DSMB to recommend stopping the trial after inclusion of 4,000 patients. A total of 4,005 patients have been enrolled. Primary endpoint is the composite of death, myocardial infarction, stent thrombosis, stroke and major bleeding at 9 months after randomization.

Results:

Results for clinical endpoints will be available in November 2014.

Conclusions:

ISAR -SAFE is the largest and the only double-blind, randomized clinical trial assessing the value of shortening DAPT duration from 12 to 6 months in patients with DES implantation. Although the trial was stopped prematurely after inclusion of two thirds of patients it has the potential to provide major insights into the optimal DAPT duration after DES implantation.

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