The Field Administration of Stroke Therapy – Magnesium (FAST-MAG) Phase 3: Primary Results "Golden Hour” Stroke Trial

Background of the Study: Magnesium (Mg) has neuroprotective effects in preclinical models. It has been shown to be safe and potentially effective if delivered early after human cerebral ischemia.

Questions to answer: Can paramedic initiation of Mg as a neuroprotective agent, in the field be an efficacious and safe treatment for acute stroke? Is field enrollment and treatment feasible and a prelude for further Phase 3 stroke trials? Will Magnesium (Mg) given within 2 hours of symptoms onset, improve long-term functional outcome in hyperacute stroke patients.

Trial Design/inclusion criteria

Multicenter, randomized, double-blind, placebo-controlled, NIH NINDS funded, phase 3 trial. 4 grams Mg in the field, with a 16 gram maintenance for 24 hours. N=1700 patients, all within 2 hours of stroke symptoms onset. Trial sites = 315 ambulances, 40 EMS agencies, 60 receiving hospitals and 2988 paramedics involved in LA and Orange counties. Stroke identified by LAPSS, ages 40-95, last known well time within 2 hours of rx initiation. Deficits lasting for at least 15 min.

Primary Endpoint

Modified Rankin Scale (mRan) at 90 days.

Results

Mean age 69 (SD = 13.6), about 58% male, median pretreatment stroke severity of LAMS = 3.7 and median early post treatment NIHSS at ED arrival = 11. IS = 73%, ICH = 23.3% with stroke mimics = 3.9%. No difference in mRan at 3 months Mg vs – Placebo. Pre-hospital Mg given in the field was not beneficial in acute stroke patients, but no increase in SAEs.

Take Away – This study is the first stroke prehospital phase 3 randomized controlled trial using a neuroprotective medication, prior to recanalization therapy, employing prehospital physician elicited informed consent, and delivering drug within the “golden hour” (<1 hr.) of treatment. This study showed that this type of trial is feasible.