SHINE: Stroke Hyperglycemia Insulin Network Effort Trial Protocol

Objective:

Specific Aim 1
To determine the efficacy of tight glucose control to a target range of 80-130 mg/dL with IV insulin infusion in hyperglycemic acute ischemic stroke patients within 12 hours of symptom onset as measured by mRS at 90 days after stroke.

Specific Aim 2
To determine the safety of tight glucose control with IV insulin infusion in hyperglycemic acute ischemic stroke patients treated for up to 72 hrs.

Study Design: SHINE is a multicenter, randomized, controlled clinical trial to be conducted at 17 Neurological Emergencies Treatment Trials (NETT) hubs and their spoke hospitals as well as approximately 10 non-NETT sites. Patients must have known history of type 2 diabetes mellitus and glucose >110 mg/dL OR admission glucose ≥150 mg/dL in those w/o known diabetes mellitus.

Intensive Group: bG 80-130 mg/dL
Control Group: bG <180 mg/dL

Number of Subjects: Total sample size for the study is 1400 subjects.

Inclusion/Exclusion Criteria

Inclusion Criteria

1. Age 18 years or older
2. Clinical diagnosis of ischemic stroke defined as acute neurological deficit occurring in one or more cerebral vascular territories. Neuroimaging must be done to exclude intracranial hemorrhage (ICH).
3. Protocol treatment must begin within 12 hours after stroke symptom onset and is recommended, but not required, to begin within 3 hours after hospital arrival. If time of symptom onset is unclear or patient is awakening with stroke symptoms, the time of onset will be the time the patient was last known to be normal.
4. Known history of type 2 diabetes mellitus and glucose >110 mg/dL OR admission glucose ≥150 mg/dL in those w/o known diabetes mellitus
5. Baseline NIHSS score of 3-22
6. Pre-stroke modified Rankin Scale score = 0 for patients with an NIHSS score of 3-7. Pre-stroke modified Rankin Scale score = 0 or 1 for patients with an NIHSS score of 8-22.
7. Able to provide a valid informed consent to be in the study (self or their authorized legally accepted representative). The approved consent form must be signed and dated in accordance with federal and institutional guidelines.

Exclusion Criteria

1. Known history of type1 diabetes mellitus
2. Substantial pre-existing neurological or psychiatric illness that would confound the neurological assessment or other outcome assessment
3. Having received experimental therapy for the enrollment stroke. IV tPA (up to 4.5 hrs) or IA tPA are allowed as are IA therapies including use of FDA cleared devices. Non FDA cleared devices are considered experimental and are excluded.

4. Known to be pregnant or breast-feeding at the time of study entry
5. Other serious conditions that make the patient unlikely to survive 90 days
6. Inability to follow the protocol or return for the 90 day follow up
7. Renal dialysis (including hemo or peritoneal dialysis)