Clinical trial guidance for Mount Sinai Nursing

Study sponsor: Washington University School of Medicine in collaboration with National Institute of Neurological Disorders and Stroke (NINDS)
Study acronym: MOST
Study title: Multi-arm Optimization of Stroke Thrombolysis (MOST)
Study arms: Drug: Argatroban Drug: Eptifibatide Drug: Placebo
Approvals: IRB, ED medical/nursing leadership, Pharmacy.

For study-related questions/issues, please contact:

- *Clinical Trials Research Coordinator*: (201) 626-0466 (Mon – Fri 8 am – 6 pm)
- *Site Principal Investigator*: Michael Fara, MD, by cellphone 24/7 at 347-861-5883

Study summary

- Phase 3 placebo-controlled, single-blinded, randomized, three arm study
- Aim is to confirm safety and establish efficacy of IV thrombolysis plus IV argatroban OR IV thrombolysis plus IV eptifibatide/integrillin over standard IV thrombolysis alone for acute ischemic stroke
- Enrolling Mon – Fri 8 am – 6 pm

Eligibility

- Research Coordinators and site investigators determine eligibility and obtain consent.
- Adults who receive TNK within 3 hours of last known well (LKW).
- Coags: INR ≤ 1.5 and Normal PTT
- Exclusionary criteria:
  - NIHSS < 6
  - mRS > 3
  - Large (> 1/3 of MCA) infarct on CT
  - Any of the relative contraindications to tPA

Assessments/Interventions

- Labs are tested in the Mount Sinai lab. This trial does not use special research tubes for blood.
- RN will follow usual post IV-thrombolytic plan of care
- Intervention 1 (baseline)
  - Nurse places dedicated IV line
  - PI administers drug
  - Nurse hangs infusion bag
- Intervention 2 (hour 2)
  - RN exchanges infusion bag
  - Blood draw (for 1/3 patients), ordered by neurology provider as indicated
  - RN may change infusion rate *if prompted by research coordinator*
- Intervention 3 (hour 6)
  - Blood draw (for 1/3 patients), ordered by neurology provider as indicated
- Research Coordinators will tell you what time windows to anticipate for phlebotomy, based on when drug is given.

Drug

Epic order is placed for GCO #19-0948

- Patient is randomized to placebo, argatroban, or eptifibatide and Research Coordinators bring the drug from pharmacy to the RN (not via tube station).
- Administration instructions
    - Vial 1 (Bolus) Administer 8.5 ml over 3 minute hand push (study MD pushes)
    - Vial 2 (0-2 hrs) Administer 15.3 ml/hr over 2 hour infusion
    - Vial 3 (2-12 hrs) At start, administer 15.3 ml/hr. Titrate per study protocol *as prompted by research coordinator*

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Risks

The main risk to the patient is intracerebral hemorrhage. Close evaluation for this is already part of standard of care for patients having received IV thrombolysis, and no additional study-specific monitoring is indicated. In the event of confirmed hemorrhage, study subjects will be immediately unblinded to all clinical providers so that appropriate clinical care can be given.

Monitoring

- No specific monitoring is required for this drug outside of usual care for post IV thrombolytic