Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

Site Monitoring

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SHINE

Site Monitoring Schedule

- Routine Interim Monitoring Visits
  - After first subject at a site has been enrolled and completed treatment period
  - At least one visit per year thereafter

- Close-Out Visit

Scope of Monitoring

- Regulatory
- Study team changes
- Facilities
- Informed consent process
- CRFs and source documents
- Recruitment rate by recruitment team

Medication Administration and Laptop Accountability

- Monitor will verify that the drug dispensed to subjects is consistent with randomization assignments
  - Save one colored sticker from the IV bag for each subject

- Monitors will verify the laptop computers are securely stored and in good working condition

Informed Consent Process

- 100% review of all subjects
- Ensure correct version of IC is signed, dated and timed by all participants
- ICF Process is documented

CRFS and Related Source Documents

- 100% review of CRFs for first 2 subjects
- 100% review of eligibility and randomization CRFs of all subjects
- All SAEs
- Sampling thereafter of CRFs ensure that the protocol and procedures are being followed

Source Documents

- The monitor will ensure that reported data is complete, accurate and verifiable from source documents
- What are acceptable source docs?
  - ED notes, EMS and flight run sheets, physician notes, nursing notes, medical history notes, MAR, laboratory results, study worksheets and electronic case report forms (must be well defined)

PI Review and Affirmation

- The site PI must review and affirm the accuracy of the information reflected in all of the case report forms for each study participant.

- The End of Study Form requires a date of PI review and affirmation

Protocol Deviations

- Enrollment/Informed Consent Deviations
- Treatment Deviations
- Computer Deviations
- Follow-up Deviations
- Research Conduct Deviations

Corrective Action and Preventive Action (CAPA) Plans

- Observed patterns of deviations should be addressed in a written CAPA plan designed to reduce the frequency of such deviations in the future

- The plan should include clear documentation of the observation and associated compromise in regulatory obligations, protocol compliance, subject protection or safety

Corrective Action and Preventive Action (CAPA) Plans

- Reasonable timelines for actions and staff responsibilities, and a method to track completed actions, should also be included in the plan

Reports/Results

- Expect within 20 business days

It’s the “little things” that count !

- POC glucose values
- Data entered into study computer
- MAR
- IV flow sheets
- Dietary consumption per nursing documentation

MUST ALL MATCH

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Our Experience thus Far - Areas of Concern

- IV Rate adjustments
- Meal insulin
- Timeliness of glucose checks
- Transitions from Level 1 to 2, Level 2 to 3
- Response to Hypoglycemia
- Data discrepancies between study computer and source documents

Our Experience thus Far

- Daily Care Log
- NIHSS not assessed 30 minutes prior to randomization
- Daily NIHSS not completed or documented in medical record

SHINE

Our Goal

- The monitor's approach to a visit is to be enthusiastic, friendly, collaborative, provide education and good feedback to help your study team provide the best quality data and subject safety in the SHINE trial.

Questions?