Stroke Hyperglycemia Network Effort (SHINE) Trial Site Monitoring

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Site Monitoring Schedule

- Study Initiation Visit
  - Readiness Call
- Routine Interim Monitoring Visits
  - At least one visit per year
- Close-Out Visit

Site Monitoring Schedule

- Timing of visits

  First visit to each site after subject #1 enrolled and completed treatment period

SHINE

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

Informed Consent Process

- Documentation of informed consent process in medical records or subject binder
  - Risks, benefits and alternative treatments have been explained
  - The subject /LAR was given ample time/ opportunity to ask questions and that the questions were answered to their satisfaction
  - The subject/LAR was given a signed copy of the consent

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
  - Subject did not meet inclusion/exclusion criteria
  - Failure to obtain documented informed consent prior to performing protocol specific activities
  - Failure to document the informed consent process
  - Incorrect consent form used
  - Informed consent form not filled out correctly or completely

Protocol Deviations
Treatment Deviations

- Admitting unit deviations (incorrect level of care)
- Subject received the wrong treatment or incorrect dose
- The subject was given or otherwise took additional glucose lowering medication
- Missed doses

Protocol Deviations
Treatment Deviations

- Unblinding of subject or family
- Dietary deviation
- Glucose checks done >15 minutes outside scheduled time (or > 5 minutes while following hypoglycemia protocol)

Protocol Deviations
Computer-related Deviations

- Internet down/cannot connect to GlucoStabilizer
- Computer down/not operational

Protocol Deviations
Follow-Up Deviations

- 6 week visit completed outside of timeline defined in protocol
- 90-day visit completed outside of timeline defined in protocol
- 90-day assessment completed by an unblinded investigator
- Visits not completed

Protocol Deviations
Research Conduct Deviations

- Failure to report serious adverse events
- Changing the protocol without IRB approval
- Falsifying research or medical records
- Performing tests or procedures beyond the individual's professional scope or privilege status (credentialing), or those not assigned on the Delegation of Authority Log

Protocol Deviations
Research Conduct Deviations

- Working under an expired professional license or certification
- Failure to follow federal and/or local regulations, and intramural research policies
- A breach of confidentiality

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

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.

Harmony

SHINE

Questions?