



This patient is enrolled in the

SHINE study

(Stroke Hyperglycemia Network Effort)

Treatment Arm: **Blue/Intervention**

Research Hotline: (347) 220-8585

www.shinetrial.com

Aim: To determine efficacy of tight glucose control with IV insulin infusion hyperglycemic acute ischemic stroke patients w/in 12 hours of symptom onset (measured by 90 day post-stroke MRS).

Target: 80 – 130mg/dL

Glucose Monitoring:

- Testing should be done as a POC finger stick.
- Q1-2 Hours, as required by GlucoStabilizer tool on study laptop.
- The mandated testing window is +/- 15 minutes from the expected time.
- PRN glucose check for any symptom suggestive of hypoglycemia.
- Document results in the study laptop **AND** the electronic medical record.

Study Treatments:

- Patient will follow study protocol glucose management **ONLY**, not insulin infusion or diabetes order sets in the electronic medical record.
- Please read study protocol order comments carefully and follow directions. Call hotline with any questions.
- Pharmacy will dispense IV medications and fast-acting insulin. Regular insulin and saline are part of floor stock. D50 will be sent up to the floor from the pharmacy once ordered at the start of the study.
- For BG < 80 mg/dl, initiate hypoglycemia protocol (below).

Hypoglycemia Protocol:

- **If the subject blood glucose drops < 80 mg/dl, complete the following:**
 - **Stop** the IV infusion and **ALL** subcutaneous injections while the BG is below 80 mg/dl.
 - For all finger sticks point of care glucose < 80 mg/dl, give dose of D50 determined by GlucoStabilizer as a slow IV push (over 1 – 2 minutes).
 - Check the glucose again in 15 minutes and repeat above until BG \geq 80 mg/dl.
 - Be sure to record **ALL** glucose measurements and D50 administrations (select new event).
 - Once BG \geq 80 mg/dl, restart IV and subcutaneous injections per SHINE protocol.
- **If the glucose drops < 70 mg/dl, complete the following:**
 - Continue the use the hypoglycemia protocol above, give D50, repeat glucose checks every 15 minutes.
 - Draw a stat **serum** glucose measurement but **do not** delay D50 by waiting for lab result.
 - Screen for hypoglycemia symptoms using the hypoglycemia symptomatic questionnaire.
 - Repeat questionnaire Q15 minutes until the glucose is \geq 70 mg/dl or the symptoms have resolved.

- Once the glucose is ≥ 80 mg/dl, the timing of glucose checks and insulin rate will be determined by Glucostabilizer.
- Screen the subject for neurological worsening (considered any clinical change that is associated with a ≥ 4 point increase from baseline or most recent daily NIHSS score).
- If the subject has not returned to baseline within 24 hours (± 4 hours from hypoglycemic event onset), a NIHSS assessment is required by study staff.

Meal Times:

- If patient is NPO + continuous tube fed, should receive saline injections glucose checks closest to 09:00 + 21:00.
- Meals should be delivered around 06:00, 12:00, and 18:00.
- Meal insulin doses are calculated based on meal consumption.
- Assess meal consumption about 20 minutes after initiation of meal.
 - Full or near full consumption, 60 grams carbs
 - No or nearly no consumption, 0 grams carbs
 - Partial consumption, 30 grams carbs
- If partial or full/near full consumption, make entry in study laptop (“Cover Carbs”), and dose rapid acting insulin based on GlucoStabilizer recommendations about 20 minutes after the start of the meal.
- Patients should not consume additional food not on their tray other than approved snacks.
- Family/Visitors should be instructed not to bring outside food and not to eat from patient’s tray.

Interruptions:

- For when treatment is temporarily interrupted for any reason (e.g. patient leaves unit and nurse cannot accompany patient or interruption of tube feeding).
- IV Drip should be stopped.
- When ready to restart:
 - POC glucose should be checked immediately.
 - If infusion has been off less than 3 hours, select “Resume” in GlucoStabilizer
 - If infusion has been off 3 or more hours, select “Start New Drip” in GlucoStabilizer

Please notify study team (347-220-8585) IMMEDIATELY for the following events:

- Patient is going to be discharged
- Any hypoglycemia events *Please also notify the resident/nursing manager.
- Any episodes of BG ≥ 500 mg/dl *Notify the resident and send stat serum glucose as well. Study team will call study safety monitor.
- Any episodes of clinical worsening. *Please notify treating team as well.
- If ≥ 3 episodes of hypoglycemia (<70 mg/dL) in 24 hours. Study team will call study safety monitor.

Please direct treatment team to call study hotline with treatment questions, refer to the education on study laptop, or alternately contact:

Sarah Zelonis
Coordinator
Cell: 215-514-8486/pager: 917-252-1088

Ethan Brandler
Principal Investigator
Pager: 917-218-5429