



This patient is enrolled in the

## SHINE study

(Stroke Hyperglycemia Network Effort)

Treatment Arm: **Blue/Intervention**

**Research Hotline: (347) 220-8585**

[www.shinetrial.com](http://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  $\geq 80$  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  $\geq 4$  point increase from baseline on the 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 at 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.
- Any episodes of clinical worsening. \*Please notify treating team as well.
- If  $\geq 3$  episodes of hypoglycemia 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

Jennifer Martindale  
 Principal Investigator  
 Cell: 617-470-2292