



This patient is enrolled in the

SHINE study

(Stroke Hyperglycemia Network Effort)

Treatment Arm: **ORANGE/Control**

Research Hotline: (347) 220-8585

www.shinetrial.com

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

Target: 80 – 179mg/dL

Glucose Monitoring:

- Testing should be done as a finger stick unless otherwise instructed by the study team.
- Q1Hr for first 4 hours.
- Q3Hr for remaining 68 hours. At 00:00, 03:00, 06:00, 09:00, 12:00, 15:00, 18:00, and 21:00.
- Insulin Dosing **ONLY** at 00:00, 06:00, 12:00, and 18:00, but drip adjusted with all checks as applicable.
- 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.
- Study team will evaluate glycemic control at 24 and 48 hour time-points to assess if the sliding scale needs to be advanced.
- Study team will contact the nurse approximately 1 hour prior to the time point to make the determination, and will have orders ready.
- Pharmacy will dispense IV medications. Regular insulin is part of floor stock. D50 will be sent up to the floor from the pharmacy once ordered at the start of the study or can be used from the Pyxis stock.
- 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 saline infusion and **ALL** subcutaneous injections while the BG is below 80 mg/dl.
 - For all finger sticks POC glucose < 80 mg/dl, give 25 ml (1/2 amp) of D50, 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 saline, resume study protocol.
- **If the glucose drops < 70 mg/dl, complete the following:**
 - Continue the use the hypoglycemia protocol above, give D50, repeat BG checks every 15 min.
 - 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 infusion rate will be determined by the control treatment screen.
- Screen the subject for neurological worsening (considered any clinical change that is associated with a ≥ 4 point increase from baseline or the 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.

Meals:

- 60 gram carbohydrate diet per meal
- Serve breakfast after 06:00 BG check/insulin dose.
- Serve lunch after the 12:00 BG check and insulin dose.
- Serve dinner after the 18:00 BG check and insulin dose.
- 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 Saline Drip should be stopped.
- When ready to restart:
 - If no checks or dosing were missed, maintain schedule for sliding scale and dosing. Resume IV saline drip with next glucose check.
 - If checks or insulin dosing were missed, do the following:
 - Immediately check BG, and resume IV saline drip according to sliding scale.
 - If a SQ insulin dose was missed, use BG result + sliding scale to determine if an insulin dose is indicated, and give injection immediately.
 - Do not give injections less than 3 hours apart. If you give a dose upon restarting, and the next dose is due in less than 3 hours, do not give insulin at next scheduled time.
 - Return to schedule for checks and SQ insulin dosing. Do not check BG levels less than 1 hour apart unless it is a scheduled dosing time.

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