

Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

Protocol Cases and Q&A

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Practice Case #1

You just enrolled a patient in the control group. You do your initiation check and start the saline drip at 9:50AM.

What are the times of the next checks and doses?



Practice Case #1 - Answer

- Initiation check – 9:50AM
- Q1 hour checks for 4 hours
 - 10:50 – adjust drip, no sq dose
 - 11:50 – adjust drip, dose (is within 30 mins of 12 noon dosing)
 - 12:50 – adjust drip, no sq dose
 - 1:50 – adjust drip, no sq dose
- Then go to regular schedule of q3hr checks per protocol
 - 3PM is next scheduled check – adjust drip, no sq dose
 - 6PM next scheduled check – adjust drip, dose



Initiation Transitions in Control Group

- These are tricky
- We have protocols
- Call the PI on call if not straight forward



Practice Case #2

You have a control patient on Day 1 and just did the 9AM check. Now at 10:30AM you have to go off the floor for TEE. You will be back at 1PM.

What are the next glucose check times and doses?



Practice Case #2 - Answers

- 9AM – check – no dose
- 10:30 – pause to leave floor
 - Stop drip and document pause
- 1PM return to room
 - Check glucose immediately
 - Restart saline drip immediately per protocol
- 1PM not dosing time but crossed a dosing time (12noon) and missed dose so give insulin now and record in study computer
- 3PM next check – no dose
- 6PM next check – dose per usual



Practice Case #3

You just enrolled a patient in the intervention group and you have done 3 q one hr checks. It is now 2 PM and you have to go to CTA and the clock is counting down (27 mins to next check).

What do you do now and when you get back?

#3a – if it is 4:15PM when you get back?

#3b – if it is 5:30PM when you get back?



Practice Case #3 - Answer

- Hit Stop/Hold, leave study computer
- #3a – it is 4:15PM when return (2h,15m since left)
 - You should be on stop/hold
 - Glucose check now
 - **Resume same drip** per computer rec (<3 hours on hold)
- #3b – it is 5:30 PM (3.5h since left)
 - You should be on stop/hold
 - Glucose check now
 - Start new drip and adjust dose per computer rec (>3 hrs)
 - Note – use same insulin bag just new drip run in computer

Practice Case #4

Patient is Day 1 in the control group. The 9AM check is 248. Next dosing time is noon, but the nurses are uncomfortable and want to give insulin with this check.

What are your options?



Practice Case #4 - Answer

- Follow the protocol!!!!
- 9AM – 248 – adjust drip as necessary – **no sq insulin dose**
- 12noon – 302 – give insulin per level 1
- Then give lunch
- At 3PM check may still be high as had lunch
- If ever over 500 – call safety monitor



Practice Case #5

You are finishing the 2nd day on the protocol and the 48 hour mark is at 10AM. The last glucose checks are:

Time	Glucose	SQ insulin
9AM	299	0
6AM	193	4
3AM	178	0
12AM	148	0
9PM	212	0
6PM	189	4
3PM	172	0
12PM	207	6
9AM	199	0

Note:
Most recent check
will be listed first

What do you do next?



Time	Glucose	SQ insulin
9AM	299	0
6AM	193	4
3AM	178	0
12AM	148	0
9PM	212	0
6PM	189	4
3PM	172	0
12PM	207	6
9AM	199	0

Practice Case #5 - Answer

- You need to move to level 3 because the last 2 checks were 199 and 238 – both over 180
- Now you need to calculate the basal insulin dose:
 - Total dosing in last 24 hours (including all 4 dosing times – $4+0+4+6=14$ total)
 - $14 \times 0.40 = 5.6$ units
- Give 5.6 units Lantus now at 10AM as the basal dose for level 3
- At 12 noon – do your next check and dose per level 3



Practice Case #6

Your patient is on day 1 in the intervention arm. He goes to MRI and you just read the images which show a brain tumor and no DWI lesion.

What do you do?



Practice Case #6 - Answer

- This is a stroke mimic
- Discuss with pt/family per standard care
- Stop all study treatment - document in med record and study computer reason for stop (stroke mimic – brain tumor)
- Initiate site standard care for glucose control
- Complete end of treatment CRF and document stroke mimic with narrative.
- Continue to follow pt per protocol – but off study treatment – 6 week f/u and 3 month f/u



Case #7

You are on Day 2 and your patient is in intervention arm. She had 20 sticks on day 1 and 8 already today and she tells the nurse that her fingers hurt.

What are your options?



Practice Case #7 - Answer

- Tell her you will try to reduce the finger sticks but that is important to keep close eye on her sugars
- Use the side that she can not feel if possible
- Use any currently present venous/arterial line to get blood drop to put on POC test strip
- Use Hep-Lock
- Use other places for sticks if hospital policy allows with the point of care testing such as palm, etc. (avoid the feet)



Practice Case #8

You have a patient on day 1 in the intervention arm and you just did a check. GlucoStabilizer[®] tells you the dose of insulin drip is recommended to be 0.3 u/hr but your pump doesn't go any lower than 0.5 u/hr.



Practice Case #8 – Rules for adjusting pump rate

- Whenever the rec is lower than the lowest infusion rate of your pump – go to zero.
- Decline rec, turn pump off, document in med record and study computer that rate is 0.
- Clock will count down to next check
- Continue to use study computer for checks and rate documentation even if 0 (decline recs).



Questions?



