Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

November 2012 – Volume 1, Issue 2

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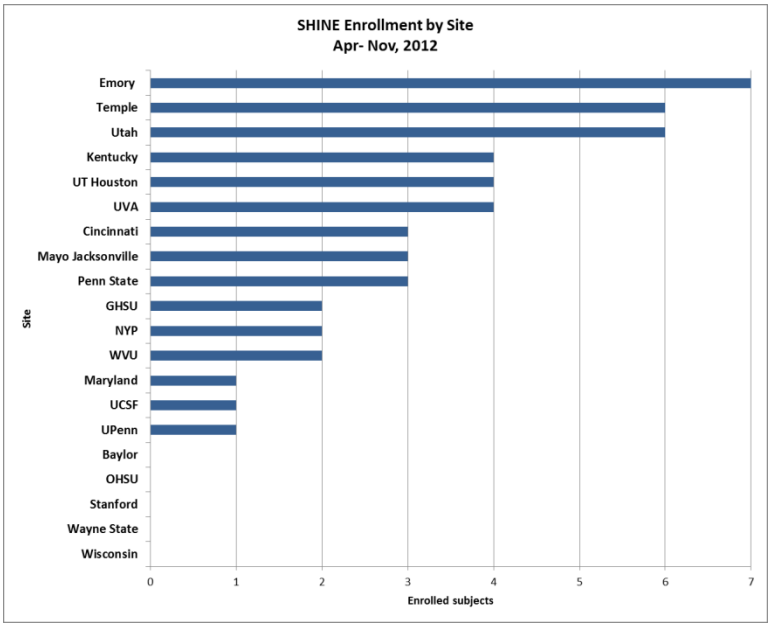
As of November 30, 2012, 49 subjects have been enrolled in SHINE across 18 enrolling sites. A total of 24 sites have completed readiness calls and are activated to enroll. Approximately one-third of the planned SHINE sites have been activated, so we will be working with you to finalize readiness preparations and schedule these calls in the coming weeks.

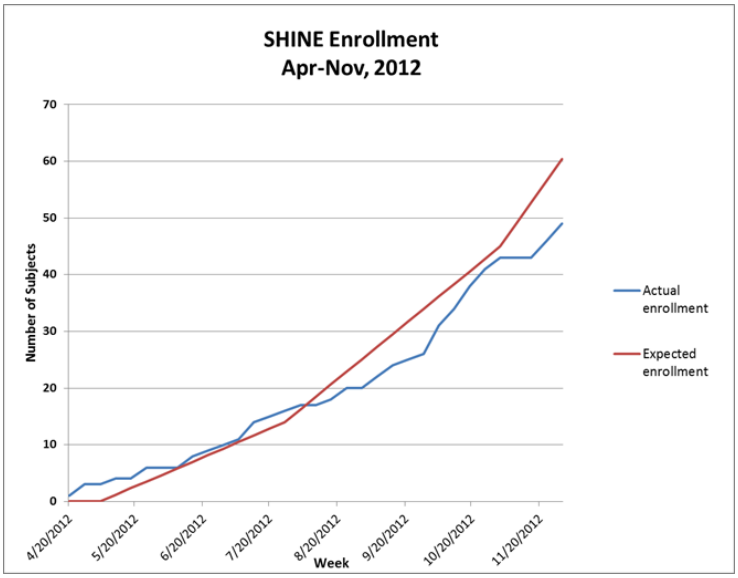
The SHINE investigator meeting for the new NETT hubs was held on Monday, November 12, in Atlanta. Many thanks to the study teams that traveled to participate in the training.

Our thanks to the following teams for their accomplishments during the past 3 months –

- The Emory team is leading study recruitment with 7 subjects enrolled to date.
- Temple is the hub with the most spokes activated, and each has now had an enrollment.
- At Kentucky, the study team enrolled 2 subjects in 1 day.

We will continue to welcome new sites over the next several months as we bring up the new NETT hubs and numerous other NETT spokes. We appreciate your efforts and continued support of the SHINE trial.





Activated SHINE sites

Baylor
Emory
- Grady Memorial*

GHSU*
Kentucky
- University of Kentucky*

Maryland
- University of Maryland*

Mayo Jacksonville*
MCW
- Froedtert Memorial

NYP
- Cornell*
- Columbia*

OHSU
- Harborview MC

Penn State Hershey*
Stanford
- Stanford UMC

Temple
- Allegheny General*
- Temple University*
- Jefferson*

UCSF
- San Francisco General*

University of Cincinnati
- University Hospital*

UPenn
- University of Pennsylvania*

UT Houston
- Memorial Hermann*

Utah*
UVA*
WSU
- Beaumont Royal Oak
- Detroit Receiving

WVU*

***indicates site with subject enrollment**

Who to contact

Protocol questions - Amy Fansler - (434) 982-6027 or acf7h@virginia.edu
Regulatory & site readiness - Arthi Ramakrishnan - (734) 936-2454 or arthrama@umich.edu
Laptop questions- Amy Fansler - (434) 982-6027 or acf7h@virginia.edu
WebDCU support – Karen Briggs - (843) 792-3980 or briggsk@musc.edu
Education and training – Joy Pinkerton - (734) 232-2138 or joypink@umich.edu

24 hour emergency contacts:
SHINE Study Hotline – 800-915-7320 (Ext 1: PI on call, Ext 2: Safety Monitor)
WebDCU Emergency Randomization Hotline - 1-866-450-2016

Reminders from the CCC and SDMC

❖ **NIHSS**

Remember that the baseline NIHSS for eligibility must be completed within **30 minutes** of randomization. Also remember that the NIHSS must be assessed daily during the 72 hour treatment period (although this is only entered in WebDCU if there is an adverse event with neurological worsening).

~ Shirley and Donna

❖ **Daily Care Log**

Treatment days 1-3 are based off of a 24 hour clock rather than calendar days. When you are adding the Day 1 visit, remember that this begins at 0 hours and will be the same date as the Baseline visit. When completing the meals section of the log, start with the first meal during the 24 hour period and then enter chronologically.

Use the Study Calendar and Subject Visit tab in WebDCU to confirm the projected visit date for the follow up visits.

~Karen B

Tips from SHINE study coordinators

"Make sure the orders are complete, you have a good system for getting them entered and that the pharmacists are on board and understand the protocol. Talk to the nurses often! Make binders or cheat sheets to have the information in front of them as clear as possible. Be there for shift change or call to talk to nurses after they get report if you can't be there in person. Make sure you have phone numbers on the study laptop so they can call with questions. Print or at least view patient history each time you round so that if things are being missed you will see it sooner rather than later. Once you have had a patient, meet with your core team (include nurse champions) what can be improved upon."

Irene Ewing – Cincinnati

"The Readiness checklist has been very helpful to make sure that all parties are aware and ready for enrollment. Train the team, especially the bedside nurses, both up front and daily during treatment period"

Suyi Niu – Utah

"Start on the pharmacy and recruitment plans early and begin collecting regulatory documents as soon as possible. And when you have an enrollment, be there for shift changes and ask the nurses to notify you with any changes (moving to another unit, discharge, hypoglycemia, etc.)."

Brent Freeman – Temple

"Keeping SHINE on the residents' mind and making sure that they are up to speed on the protocol has really helped with screening. They get the first pages so this expands the net and making sure they understand eligibility helps to ensure that we don't miss a potential patient."

Tim Fokken – NYP

Frequently Asked Questions

Q: We have a patient in the intervention arm and just did a glucose check. GlucoStabilizer is recommending that the insulin infusion rate is decreased to 0.3 u/hr. The pump doesn't go any lower than 0.5 u/hr. What do we do?

A: In any case when the GlucoStabilizer recommendation is lower than the lowest infusion rate of the pump, decline the recommendation. Enter 0 for the infusion rate when confirming the blood glucose and administration rate. Turn off the drip and document that the infusion was stopped in the medical record. The GlucoStabilizer will continue to count down to next check, and the visible alert will appear and the audible alert will sound when the glucose check is due. Check the glucose, enter and re-enter the value, and if the recommended rate is one that your infusion pump can accommodate, restart the infusion at that rate. If the recommended rate continues to be lower than the lowest rate for your infusion pump, repeat the steps above to decline the recommendation and check again per GlucoStabilizer.

Q: Our patient is on Day 1 in the intervention group. He goes to MRI, and the imaging shows a brain tumor and no DWI lesion. What do we do?

A: When there is a change in diagnosis from acute cerebral ischemia, all study treatments must be stopped. The reason for stopping must be documented in the medical record and study laptop. As with any transition when the patient is not ready for discharge but the study treatment must be stopped, initiate site standard care for glucose control. In WebDCU, complete the End of Treatment visit and document the final diagnosis with narrative. Continue to follow the patient per protocol but off study treatment (6 week and 3 month follow up visits).

I-SPOT

Insights on ***S***elected ***P***rocoagulation markers and ***O***utcomes in ***S***troke ***T***rial

I-SPOT is an optional ancillary study to SHINE which will compare blood coagulation factors and determine the relationship between levels of markers of blood coagulation and functional neurological outcome in a subset of SHINE treatment and control patients. Dr. Nina Gentile (ngentile@temple.edu) is the study principal investigator, and Hannah Reimer (hreimer@temple.edu) is the I-SPOT project manager.

More details to follow….