Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

February 2015 – Volume 3 Issue 2

IN THIS ISSUE

We are very excited to be working with our SHINE sites to incorporate the new data presented at the 2015 International Stroke Conference in Nashville, TN. The field of acute stroke is rapidly evolving and the SHINE team is thrilled to continue our work so we can contribute to the data that will improve care for stroke patients.

In this issue, we will review our current recruitment status for SHINE and share some inspiring stories of recruitment and retention that have come directly from our study teams. We have included information for site personnel regarding determining visit dates so we can maximize outcome data and are sharing reminders about the study laptops. Finally, we will share some comments on the new endovascular data but please be aware that the SHINE trial continues without disruption as these data do not substantially change how patients will be enrolled in the SHINE trial.

Congratulations to the teams at **Saint Thomas Neuroscience Research Center** and **University of Arizona—South Campus** on their first enrollments during this quarter.

We hope you all are enjoying the winter, and we look forward to hearing from you on our calls, webinars and the PI on call line.

Best,
Karen C. Johnston, MD, MSc, SHINE Administrative PI
On behalf on the SHINE team

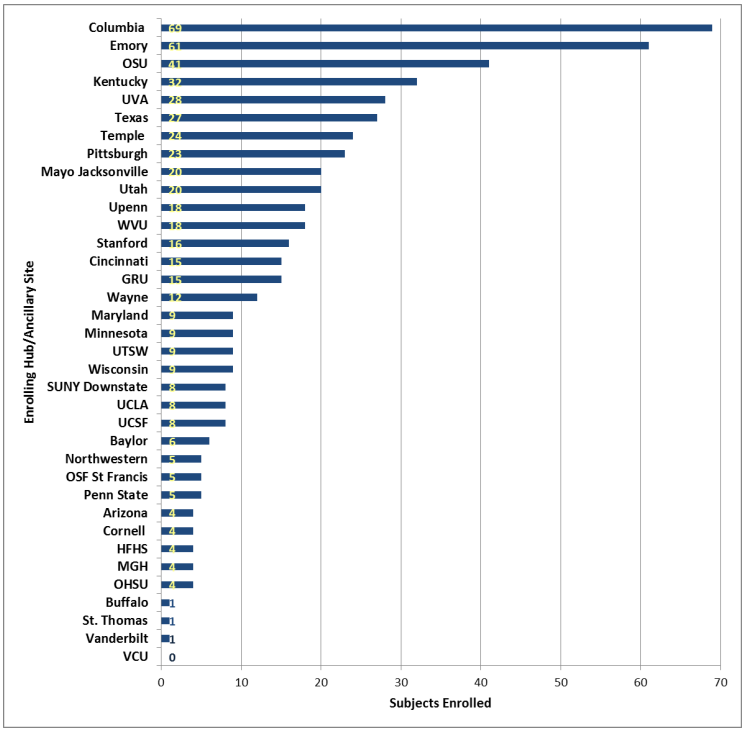
SHINE Bravo Zulu Flag

The Bravo Zulu flag has traditionally been used by US naval forces to indicate a job especially well done. The flag is flown to publically indicate the excellent work of the team.

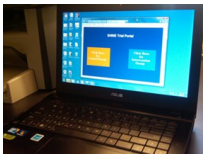
Our congratulations go to the **Northwestern University** team for capturing the Bravo Zulu flag for this quarter. Led by site PI, **Shyam Prabhakaran, MD,** and the primary study coordinator, **Carlos Corado**, Northwestern has demonstrated success in nearly all aspects of the trial in a very short period of time. Their site was the first of several newly identified StrokeNet sites not currently participating in SHINE to be activated; they enrolled their 1st subject and subsequently 4 more in a few short weeks this fall with excellent data quality; and they have proven their success with retention as well. Many thanks, and keep up the great work!

Amy Fansler, SHINE Project Director

SHINE Enrollment by Site—Apr 2012-Feb 2015



Maintaining your SHINE study laptops



A properly operating study laptop is one of the most important ways to ensure that the enrollment and treatment protocol go smoothly. Here are a few reminders to help ensure that your laptops are up to date:

- **Windows updates**— Windows does not auto-update on the study laptops. Please maintain a schedule to check and update the laptops approximately every 6 weeks and at the time of each enrollment.
- **Wireless connection**—Confirm there are not changes in your secure wireless network if there is a lapse in time between enrollments.
- **Internet explorer (IE) 11**— Note that IE 11 is not compatible with GlucoStabilizer. Settings can be adjusted to correct if IE11 is installed.

Contact Amy Fansler (acf7h@virginia.edu) with questions.

SHINE and Daylight Saving Time

Daylight saving time begins on **Sunday, March 8, at 2:00AM** local time. Because the time change will affect management of the trial protocol, the investigators on call will support study teams. Please contact the study hotline (800-915-7320) if you have an enrolled study patient during this time.

The Extraordinary Efforts from our SHINE Study Teams

Julie Scherber, the SHINE primary study coordinator at the **University of Minnesota**, went above and beyond to keep the most recent enrollment engaged in the study and agreeable to follow up. The subject had previously commented to another coordinator how much she liked Julie and appreciated her visits.

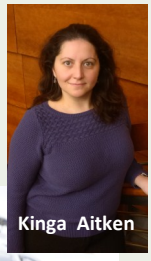
The patient went AWOL from rehab, leaving only a thank you note for her doctor. Julie made several phone attempts to check on her wellbeing without success.

Julie Scherber

After several weeks, Julie did some research to identify where patient possibly lived, drove to the neighborhood (about 30-35 miles away) and was then able to reach the patient by phone. Thanks to Julie's extraordinary efforts, the subject agreed to talk with Julie and remain available for follow-up. To ensure that they were able to capture the outcome, Julie immediately called the blinded coordinator who was able to complete the 6 week follow up by phone within an hour.

Our thanks to **Julie, Kathleen Miller** and the **entire team at Minnesota** for their commitment to the trial. We enjoy sharing success stories like these and also recognizing the hard work of our study teams.

SHINE-ing through Challenges—My phone wakes me up bright and early on a Friday morning. One of the neurology residents is notifying me of a potential SHINE patient. I acknowledge and start screening while getting ready for work. I soon realize that we have a major logistic problem. This patient had been admitted to the Medical ICU (MICU) due to a bed crunch in the Neuro Critical Care Unit (NCCU) where post-tPA patients are usually housed. The resident informs me that the patient is not going to be transferred to the NCCU anytime soon. Bummer! The NCCU nurses are very familiar with the SHINE study and have been trained on it numerous times, but the MICU nurses hadn't heard about SHINE until this point in time.



Kinga Aitken

We had roughly 3 hours to consent the patient, train the MICU nurses on the protocol, enroll and study procedures. We decided WE COULD DO THIS! With a lot of commitment, the support of Dr. Wold, supervision and training from our study team, we pulled this off. Thankfully the nurses were very open to research and understood the importance of the study and following the protocol to the t. We were tired, but happy. Just another SHINE-ing day at **University of Utah**!

Jana Wold

Kinga Aitkin—SHINE Study Coordinator,

SHINE Visit Dates in WebDCU

- Baseline and Day 1 visit dates are always the same (with the exception of rare case when at midnight).
- Day 1 starts as soon as you randomize. Day 2 is 24-48 hours from randomization. Day 3 is 48-72 hours from randomization.
- View the projected visit dates by clicking on the tab [Study progress] --> [Subject visit] ---> filter for subject

If visit dates are entered incorrectly, please contact **Kavita Patel** (pateka@musc.edu, 843-876-1167)

NEW SHINE Frequently Asked Question (FAQ)

Q: How do we pause the protocol if we randomize a study patient and then they go to endovascular therapy before starting treatment?

A: The treatment protocol period begins at the time of randomization in SHINE. For a subject who is randomized and then needs to pause the treatment protocol prior to starting the study infusion, the process is slightly different than a standard pause. Pharmacy should be notified and study treatments should be ordered immediately after randomization. However, if it is not possible to start the infusion before pausing (i.e. if the patient goes to endovascular suite for procedure), there will be no entry in the study laptop prior to the pause. Once the patient has completed the endovascular procedure and is ready to start study treatment, a POC glucose check should occur and the protocol should be initiated. A comment should be entered into the notes section when making the first entry into the study laptop to document the reason that treatment was paused prior to initiation. Detailed pause procedures can be found in the MOP (Section 5–Study Treatment).

SHINE Recognition System

Congratulations to **Ohio State University HUB** for winning the NETT hub/spoke complex division and to the **Northwestern Ancillary site** for winning the individual site division.

The following SHINE team members have been recognized with bonus points for going above and beyond in the last quarter: **Erica Eber (Cornell), Julie Scherber (Minnesota), Susan Law (SUNY Downstate)** as well as the **Minnesota** and **Georgia Regents University** teams for their hard work over the holidays. Please continue to send your great team stories to **Katrina van de Bruinhorst** at katrina.vandebruinhorst@utsouthwestern.edu.

SHINE Eligibility Quiz (see page 3 for answers)

Which of the following is the only acceptable glucose for enrollment?

a. finger stick in the ambulance.
b. finger stick on arrival in your ED.
c. point of care venous sample in your ED.
d. serum laboratory venous sample in your hospital.

Comments from the SHINE trial on MR CLEAN, ESCAPE and EXTEND Results

While the new data on acute stroke intervention do not directly affect the SHINE trial, please consider the following as your site reviews the new data.

The recently published MR CLEAN trial (Berkhemer, OA, N Engl J Med 2015; 372:11-20), ESCAPE trial (Goyal, M, N Engl J Med 2015; DOI: 10.1056/NEJMoa1414905) and EXTEND trial (Campbell, BCV, N Engl J Med 2015; DOI: 10.1056/NEJMoa1414792) require that all of our sites reconsider standard care for acute ischemic stroke patients. The SHINE trial team would like our enrolling sites to be aware that **these new data do not substantially change how patients will be enrolled in SHINE** and that the SHINE trial will continue as planned. Our design and plans for statistical analysis have incorporated the possibility that cerebral endovascular treatments might be efficacious or harmful and therefore patients receiving these treatments are still potentially eligible for SHINE. Please consider the following when re-evaluating acute ischemic stroke patient flow at your site:

MR CLEAN, ESCAPE, EXTEND

- Data support endovascular treatment of imaged proximal occlusion in the anterior circulation (ICA, MCA) (note – only 3 subjects were treated with ACA occlusion in 1 trial)
- Data support IV tPA prior to endovascular treatment as standard care
- Endovascular treatment must be provided very early with 2 trials having median time to reperfusion of just over 4 hours and the 3rd requiring completion of procedure by 6 hours
- MR CLEAN required treatment completion by 6 hours (median stroke onset to groin puncture – 4 hrs 20 min)
- EXTEND required groin puncture within 6 hours (median time from stroke onset to reperfusion 4 hrs 8 mins)
- ESCAPE required randomization within a 12 hour window (the median time from symptom onset to reperfusion was 4 hrs 1 min)
- Data support imaging suggesting modest core and adequate collaterals

SHINE

- SHINE requires that devices used for endovascular treatment are FDA cleared.
- SHINE eligible patients may be randomized before or after endovascular treatment. If randomized prior to endovascular treatment, study treatment may be paused until it is possible to resume the treatment protocol (For detailed pause procedures, see MOP – Section 5).
- SHINE requires an NIHSS score within 30 minutes prior to randomization into the trial. Intubated patients are not eligible if no NIHSS score has been completed within 30 minutes prior to randomization before intubation occurred (full NIHSS score cannot be completed for patients that are intubated as dysarthria is untestable when intubated).

We anticipate that the SWIFT PRIME results will not substantially change these considerations but will summarize those results when published if they require additional comment.

Your research team may want to prospectively consider how research options will be incorporated into the patient care flow.

We are happy to work with your team if you feel these trial results will affect your acute stroke flow in a way that you think will impact your SHINE recruitment.

SHINE – it's everywhere….

The ISC meeting in Nashville resulted in SHINE getting the spotlight in several unusual ways:

Please send your SHINE photos to Amy Fansler at acf7h@virginia.edu.

Who to contact

Protocol questions – Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
Budget & contracts questions - Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
Recruitment and retention – Katrina van de Bruinhorst – (214) 648-9248 or katrina.vandebruinhorst@utsouthwestern.edu
General education and training – Joy Pinkerton – (734) 232-2138 or joypink@umich.edu
I-SPOT questions – Hannah Reimer – 215-707-5483 or hreimer@temple.edu
Laptop questions – Amy Fansler – (434) 982-6027 or acf7h@virginia.edu
Regulatory & site readiness – Arthi Ramakrishnan – (734) 936-2454 or arthrama@umich.edu
WebDCU support – Kavita Patel – (843) 876-1167 or pateka@musc.edu

24 hour emergency contacts:
SHINE Study Hotline – 800-915-7320
WebDCU Emergency Randomization Hotline – 1-866-450-2016
I-SPOT Study Hotline – 774-234-7768

http://www.shinetrial.com/
https://webdcu.musc.edu/
https://clinicaltrials.gov/ct2/show/NCT01369069

Eligibility Quiz Answer *(see page 2 for question): b*

Thanks to all who are screening for I-SPOT. Remember:

IF YOU WANT TO SHINE DON'T MISS A SPOT

Hannah Reimer
I-SPOT Project Manager