Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

June 2017 – Volume 5, Issue 3

IN THIS ISSUE

Dear Colleagues,

As summer arrives we are excited to provide you with updates on the SHINE trial and share information that we think may be useful to our study teams.

In this issue of the newsletter, we highlight and congratulate our sites on their enrollment progress toward our milestone goal, #roadto1000.

We are pleased to share that the SHINE DSMB met on April 19th and has congratulated all of you for your excellent work and have asked us to continue the trial as planned.

Welcome *new* fellows and residents to our national SHINE teams, we encourage all members to follow us on Twitter (@SHINE_TRIAL) and use the SHINE recruitment App to help screen potential SHINE subjects.

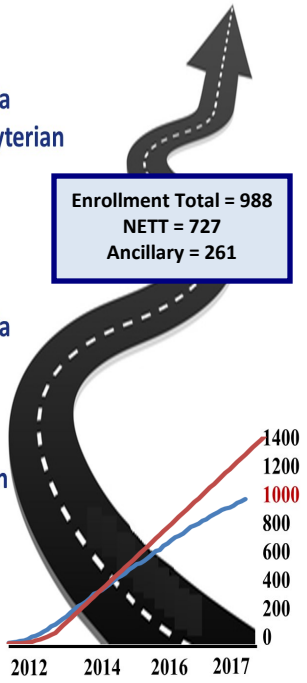
Currently, we have 45 sites actively enrolling in SHINE, including 32 NETT sites and 13 SHINE Ancillary Sites. Congratulations goes out to JFK on their first SHINE enrollment, it was a great success!

As always, we welcome your input on any issues or ideas related to SHINE. Thanks again for all your continuing efforts.

Karen C. Johnston, MD, MSc, SHINE Administrative PI

#roadto1000

951 Valley Baptist
952 Memorial Hermann
953 Lincoln
954 Temple
955 Grady
956 UCLA Ronald Reagan
957 UCLA Ronald Reagan
958 Iowa
959 UVA
960 Cincinnati
961 U of Minnesota
962 Cincinnati
963 Sinai-Grace
964 NYP Columbia
965 UVA
966 JFK
967 NYP Columbia
968 UPMC Presbyterian
969 Iowa
970 Hennepin County
971 NYP Columbia
972 UCLA Ronald Reagan
973 UVA
974 UVA
975 WVU
976 Temple
977 NYP Columbia
978 UPMC Presbyterian
979 Froedtert
980 Kentucky
981 Stanford
982 Froedtert
983 NYP Columbia
984 Temple
985 Sinai-Grace
986 Stanford
987 Northwestern
988 Mount Sinai



SHINE Population Demographics:

For those of you who missed the ISC's SHINE poster, below are the SHINE subject population demographics.

Characteristics	N = 914
Median age (years)	66
Male (N, %)	489 (54%)
White (N, %)	594 (65%)
Black/African American (N, %)	263 (29%)
Hispanic or Latino (N, %)	135 (15%)
Past Medical History	
Diabetes mellitus type 2	726 (79%)
Enrollment Information	
Median eligibility glucose (mg/dL)	187
Median Stroke Symptom Onset to Randomization - minutes	417 (6:57 hours)
% Receiving IV tPA	569 (62%)
Stroke Severity	
Median NIHSS	8
NIHSS 3-7 (mild) (N,%)	454 (50%)
NIHSS 8-14 (moderate) (N,%)	272 (30%)
NIHSS 15-22 (severe) (N, %)	187 (20%)

Hot Enrollers for April—June 19, 2017:

Hub	Site	#
NYP	Columbia	5
Ancillary	UVA	4
Temple	University Hospital/JFK	4
UCLA	Ronald Reagan	3

Top Enrollers as of June 19, 2017:

Hub	#
NYP	117
Emory	115
Ohio State	65
Kentucky	49
UVA	49
Texas	47
PITT	46

SHINE Subject Change in Diagnosis?

Remember—TIA or stroke with hemorrhagic conversion are NOT stroke mimics. Each of these diagnoses are included in our target population. Also please remember that a DWI negative stroke is an acceptable cerebral ischemic diagnosis if the clinical team feels this is the most likely diagnosis. Please call Heather Haughey with questions.

Diagnosis	Treatment	Follow-up
Stroke	Treat for 72 h or 6 h prior to d/c	Full Follow-up
TIA	Treat for 72 h or 6 h prior to d/c	Full Follow-up
Stroke w/hemorrhagic conversion	Treat for 72 h or 6 h prior to d/c	Full Follow-up
DWI neg. stroke	Treat for 72 h or 6 h prior to d/c	Full Follow-up
Stroke mimics	Stop Rx protocol	Full Follow-up

Karen C. Johnston, MD, MSc, SHINE Administrative PI

SHINE News and Notes

NETT Infrastructure remains in place for the duration of all currently funded trials—including SHINE.

The SIREN network will not compromise existing support for SHINE.

SHINE trial results will inform acute ischemic stroke care for a large number of patients:

~800,000 new & recurrent strokes in the United States each year
~680,000 ischemic strokes in the United States each year
~275,000 ischemic strokes have hyperglycemia in acute setting

As one can see from the numbers, evidence-based management of hyperglycemia in acute ischemic stroke will have a substantial pub-health impact on stroke care in the United States. Your hard work to date has put SHINE at 71% to trial completion. Keep up the great word and LET'S FINISH! **Kevin Barrett, recruitment PI**

DSMB Meeting 4/19/17

DSMB Recommendations:

- No Safety Concerns
- Congratulations on success to date
- Continue data quality and monitoring efforts
- Continue as planned

Spokes for Strokes Spin-a-thon

The SHINE team and SHINE logo were recently sported at a fund-raiser to Support UVA research for Cervical Artery Dissection and Young Stroke. In attendance were UVA Neurologists, nurses, and coordinators and grateful patient Skylar Doerwaldt. The SHINE UVA team was also well represented by none other that Karen C. Johnston and Sonya Gunter pictured here! This event was a fun active event that has raised over $7,500 dollars. The **UVA Stroke Center** thanks all who donated.

I-SPOT

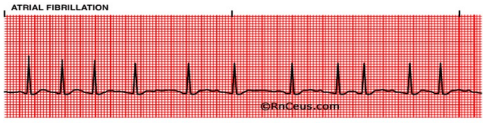
Insights on Selected Procoagulation markers and Outcomes in stroke Trial

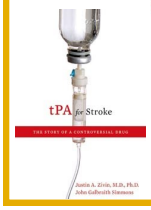
Total Enrollment:192
IV tPA subjects: 53

Screening subjects with A-Fib

◊ If not already on anticoagulants check with the team to see if they anticipate starting anticoagulants within the 48 hours. If not, they can be enrolled in I-SPOT.

◊ If a subject is enrolled and later started on anticoagulants then call the hotline (preferably before first dose is given)





Please check your lab kit supplies and email Hannah if you need more kits: hreimer@temple.edu

Questions call the I-SPOT hotline: (774) 234-7768

Hannah Reimer, I-SPOT Project Manager

D50 National Shortage?

This shortage may or may not affect your site. If your site is one that is affected by the shortage, we would recommend that you work with your pharmacy to consider the use of these or other alternatives. **Documenting dextrose administration in the SHINE trial portal:**

Dextrose [C]	Control	Intervention
D40	Give D40 12.4GM (31mL)	MULTIPLY GlucoStabilizer recommendation by **1.25** to get dose of D40.
D25	Give D25 12.5GM (50mL)	MULTIPLY GlucoStabilizer recommendation by **2** to get dose of D25.
D20	Give D20 12.6GM (63mL)	MULTIPLY GlucoStabilizer recommendation by **2.5** to get dose of D20.
D10	Give D10 12.5GM (125mL)	MULTIPLY GlucoStabilizer recommendation by **5** to get dose of D10.

INTERVENTION GROUP: Assuming you give the recommended total dextrose dose, **DO NOT CHANGE** the value for the recommended rate of D50 even if a different dextrose-containing solution was administered. **Make a note in Comments field** to document the concentration and volume administered. (E.g. IV D10 50mL)

CONTROL GROUP: Assuming you give the recommended total dextrose dose, **Enter D50 (ml) dose: 25 DO NOT CHANGE,** even if a different dextrose containing solution is given, we want to document the equivalent dose of D50. **Make a comment in Notes field** to document the concentration and volume administered. (E.g. IV D10 125mL)

Please call Heather M Haughey with any questions!

Research – Clinician Partnership Best Practices: Bi-directional communication is key

Research Team & Clinical Nurses Partner to:

⇒ Discuss maintaining the blind for patient/family

⇒ Discuss SHINE portal data entry, BG checks, drip pauses, meals

⇒ Discuss Hypoglycemia Protocol < 80 vs < 70

⇒ Discuss transfer at nursing shift changes

⇒ Discuss SHINE diet, alert team of D/C home

⇒ Discuss when to call research team or SHINE Hotline

⇒ Discuss need to call the **SHINE Hotline:** BG < 70 three times within 24h, BG < 40 or BG ≥ 500

Thank you for continuing these conversations. **Karen C. Johnston, MD, MSc, SHINE Administrative PI**

Research – Clinician Partnership Site Testimonials

Insights from NYP Columbia—Angela Velazquez

The Clinical Research Team at NYP/Columbia University is proud to be part of SHINE Study. Our team is led by our Principal Investigator Dr. Jan Claassen who's consistently enthusiastic and always available to screen and enroll subjects into SHINE study. Our in-house sub-investigators serve as a bridge between the clinical staff and research team to provide continuous monitoring for potential subjects coming into the hospital. Our outstanding and dedicated research coordinators are available 24 hours a day, 7 days a week to constantly remind the clinical staff of a possible enrollment and help implement the study protocol. Lastly, but most importantly, our excellent nursing staff exhibits hard work and dedication that facilitates our success in this clinical trial.

Insights from Cincinnati—Sara Keegan

The SHINE clinical research team at Cincinnati is led by the local PI, Opeolu Adeoye. Opeolu is part of our comprehensive stroke team comprised of EM physicians and neurologists. Some of the stroke team members also serve as the neurocritical care intensivists in the Neuro-ICU where all SHINE patients are admitted. The physician stroke team is available 24/7/365. To complement the physician stroke team we also have our CRCs that are available 24/7/365 for SHINE enrollments. They reside in the emergency department and are available for screening, enrollment activities and follow-up. The lead coordinator will also touch base with the ICU nurses for each SHINE patient at each shift change for the duration of drug infusion to answer any questions or do just-in-time training. Cincinnati also holds a weekly stroke team meeting where we can discuss research cases.

Insights from Stanford—Carine Ho

Accurate and timely screening for clinical trials is critical to trial success, and stroke clinical trials present unique challenges due to patient characteristics, time-sensitivity, and multidisciplinary clinical care. At Stanford University, we have two different groups of research coordinators who screen and enroll patients for stroke clinical trials – one group affiliated with the Neurologic Emergencies Treatment Trials network and one group affiliated with the Stanford Stroke Center research team. Like all busy stroke centers, the clinical demands often limited prioritization of clinical trial screening by our front-line clinicians and resulted in parallel workflows between the clinical and research teams. In order to improve communication and coordination between the clinicians and the research team, we developed a mobile tool that semi-automates screening for stroke clinical trials. The clinical team completes the screening tool immediately after initial stabilization and treatment of a stroke patient. The results of the screening survey are then emailed to the research teams. This novel tool and workflow has resulted in improved communication between clinical and research teams, as measured by clinician and research team satisfaction, reduction in number of text messages and emails to the clinical team about study screening, and increase in percentage of patients who are actively screened for trials. the neurology team has created a survey consisting of eligibility questions for different studies that clinicians respond to after consulting on any stroke alerts. While the research team screens those patients, that survey is emailed to our team. This ensures that the clinicians do not get too many texts/emails from the research team regarding study potentials and that all study potentials are screened.

In addition, the clinical and the research teams meet on a weekly basis to discuss enrollments, AEs/SAEs, and address any issues that arise during the treatment period. These meetings ensure both teams are in continuous communication and work together to improve the flow of our enrollments.

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Askiel Bruno — abruno@augusta.edu Christiana Hall— christiana.hall@utsouthwestern.edu
Protocol, laptop & study drug stickers — Heather M. Haughey — hmh8f@virginia.edu
SAE reporting & regulatory — Ruth Lewis — rrlewis@med.umich.edu
Recruitment/retention — Katrina van de Bruinhorst — katrina.vandebruinhorst@utsouthwestern.edu
CRF completion/data management — Kavita Patel — pateka@musc.edu
Ancillary contracts/invoicing — Emily Gray— eaw8t@virginia.edu
I-SPOT— Hannah Reimer— hreimer@temple.edu

24 hour Emergency Contacts:

SHINE Study Hotline — 800-915-7320
WebDCU Emergency Randomization Hotline — 1-866-450-2016
I-SPOT Study Hotline — 744-234-7768