



Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

July 2013 – Volume 1, Issue 4

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Congratulations on a successful year 2 of SHINE. We have accomplished a great deal in the past year. There are now 46 enrolling sites, and at the end of Y2, we had 182 total subjects enrolled. We are averaging about 20 enrollments per month. We thank all of you for your hard work and creativity to

make SHINE a success at your individual sites.

Special Kudos to the study teams at NYP and Emory who continue to lead the pack with over 45 enrollments combined. Kentucky, Temple and Utah have also made significant contributions to our recruitment efforts. Ohio State and Pittsburgh are leading the new NETT hubs in enrollment. In addition to enrollment accomplishments, we would also like to recognize the teams at Wayne State, UCSF and Temple for their support in bringing up multiple spokes, and UT Houston for their efforts in identifying several new potential sites for SHINE.

In year 3, we will continue to focus on maximizing recruitment. We have plans to activate an additional 15-20 sites including spokes of NETT hubs and new ancillary sites. We have a target of enrolling 33 subjects per month, so we will be counting on all of our sites to help us meet our recruitment goals. Every enrollment counts. We will continue to visit sites in the next year and look forward to visiting with you and meeting new study team members.

Again, our thanks from the entire SHINE team. We appreciate all that you do to make this trial a success.

Sincerely,

Karen C. Johnston, MD, MSc, SHINE Administrative PI
On behalf of the SHINE leadership

New SHINE Enrolling Sites

We would like to extend a warm welcome to the following new sites that will be participating in SHINE.



(Spoke of Cincinnati)



(SHINE ancillary site)



(Spoke of UT Houston)



(Spoke of Minnesota)

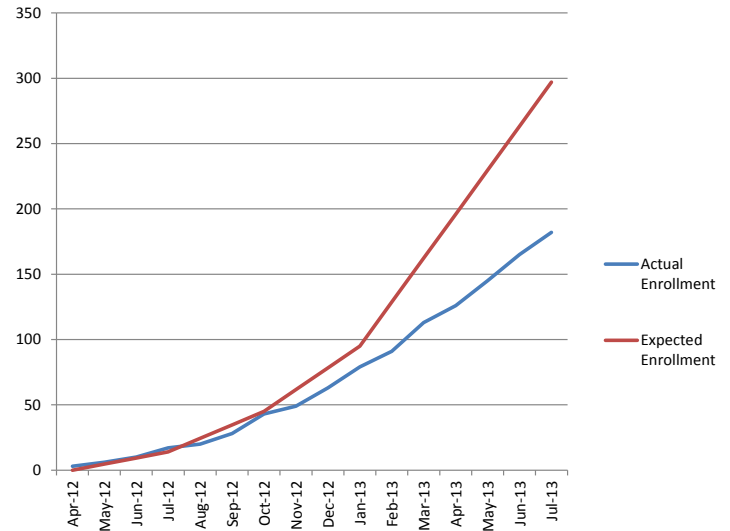


(Spoke of UT Houston)



(SHINE ancillary site)

SHINE Enrollment Apr 2012-Jul 2013

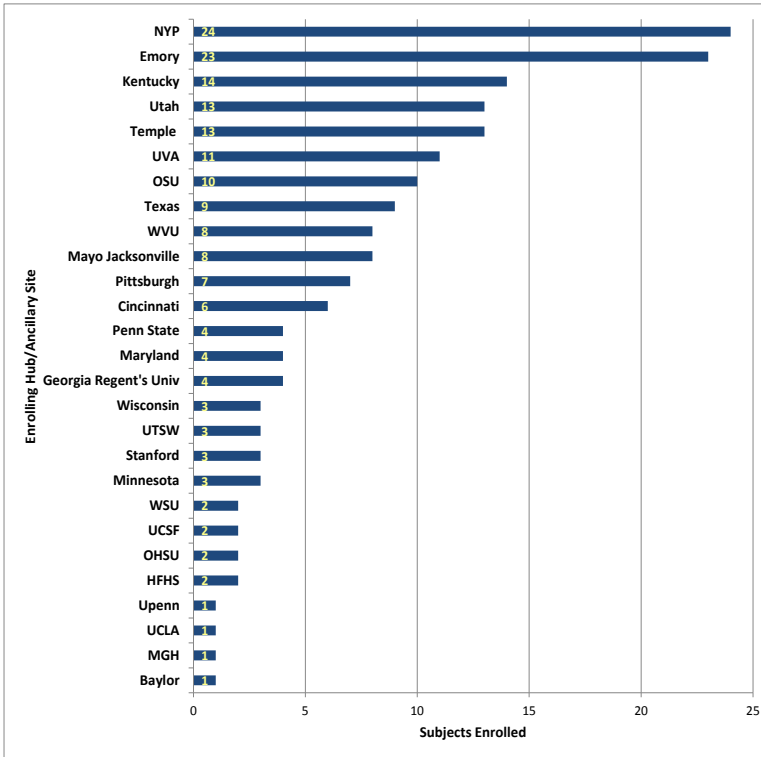


SHINE Enrolling Sites

Baylor	Baylor*	SUNY	Kings County
Cincinnati	University Hospital*	Temple	Allegheny General*
Emory	Emory Univ		Hackensack UMC
	Grady Memorial*		Temple University *
GRU	Georgia Regents*		Thomas Jefferson*
HFHS	Henry Ford Hosp*	UCLA	UCLA MC*
	Univ of Michigan*	UCSF	CPMC Davies
Kentucky	Univ of Kentucky*		CPMC Pacific
Maryland	Univ of Maryland*		San Francisco Gen*
Mayo Jacksonville	Mayo Jacksonville*		UCSF MC
MCW	Froedtert Memorial*	UPenn	Hospital of UPenn*
MGH	Mass General*	UT Houston	Austin Brackenridge
	HCMC		Austin Seton
Minnesota	UMMC Fairview*		Memorial Hermann*
	NYP	Utah	University of Utah*
	NYP Weill Cornell*	UTSW	UTSW-Zale*
OSF	OSF Saint Francis	UVA	Univ of Virginia*
OHSU	Harborview MC*	VCU	VCU Medical Center
OSU	Wexner MC*	WSU	Beaumont Royal Oak
Penn State	Hershey MC*		Beaumont Troy
Pittsburgh	UPMC Mercy*		Detroit Receiving*
	Presbyterian*	Sinai Grace	
Stanford	Stanford UMC*	WVU	West Virginia Univ*

*indicates site with subject enrollment

SHINE Enrollment by Hub/Ancillary Site



SHINE Follow-Up Visits

Must be completed by a blinded assessor
Use the Subject Visit tab under Project Management in WebDCU™ to confirm the projected date of the visit

6 week phone call (+/-14 days)

- ❖ Assessments - mRS and SAEs

3 month visit (+/-14 days)

- ❖ Assessments
 - mRS, NIHSS, BI, SSQOL, unblinding questionnaires
 - Glucose control meds, SAEs
- ❖ Late data will be accepted (up to +30 days for mRS and up to +90 days for other outcomes) but is a protocol deviation



Frequently Asked Questions

Q: Can a patient with an in-hospital stroke be enrolled in SHINE?

A: Yes, patients with an in-hospital stroke should be screened for SHINE. Randomization must occur within 12 hours of symptom onset. The date and time of hospital arrival should be documented on the Eligibility CRF. Contact the PI on call for questions about assessing the pre-stroke mRS for patients who have had an in-hospital stroke.

Q: We are screening a potential SHINE candidate who was diabetic and on medication several years ago. Now with diet and exercise, he is off all medication and has a normal HbA1c. Does this count as having a diagnosis of diabetes?

A: For the purposes of the SHINE trial, these patients should be considered 'non-diabetic' and only eligible with a glucose level ≥ 150 mg/dL. Just as someone with gestational diabetes had a diagnosis in the past and is at risk of again developing diabetes, these patients should not be considered to have a current diagnosis of T2DM.

CONTROL GROUP -Timing of hourly glucose checks

As a reminder, one POC glucose test is required prior to randomization for eligibility. After randomization, once the study infusion is ready to be started, check the glucose and use that result to determine the rate of IV saline. Check again in one hour intervals from the infusion start time for the next 4 hours, adjusting the IV saline with each check, and then transition to q3 hour checks per the study schedule (3, 6, 9, 12, 15, 18, 21 & 24). SQ insulin should only be given at dosing times (6, 12, 18, 24).

Time that study infusion was started: ____:____

First hourly check: ____:____

Second hourly check: ____:____

Third hourly check: ____:____

Fourth hourly check: ____:____

First q3 hour check will be due: ____:____

Assess level changes at 24 and 48 hours from randomization but maintain schedule for q3 hour checks.



Insights on Selected Procoagulation markers and Outcomes in Stroke Trial

Enrollment Update

Total subjects enrolled: **8** Enrolling sites: **32**

"Congratulations to the following sites with I-SPOT enrollments: Temple, Cincinnati, Ohio State, NYP, Wisconsin and Emory! Remember that because not all subjects are eligible for I-SPOT the ones who are that much more important. Thank you to all sites for diligently screening for I-SPOT."
~Hannah Reimer

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@muscc.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