Stroke Hyperglycemia Insulin Network Effort Trial Newsletter

November 2013 – Volume 2, Issue 1

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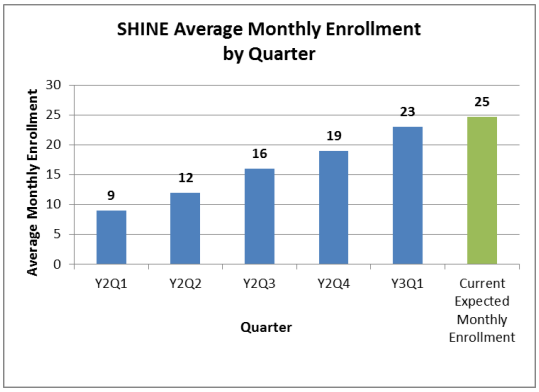
Enrollment and Trial Updates

Congratulations to new sites, sites with exceptional enrollment

In the past several months, we have crossed two important milestones—enrollment of 250 subjects, which is nearly the halfway point for the first interim analysis, and activation of our 50th site.

Since the beginning of the second year of the trial in August 2012, enrollment has consistently increased each quarter. By the first quarter of year 3, our average monthly enrollment reached 23 subjects per month. This is nearly where we need to be to meet our current expected monthly enrollment target.



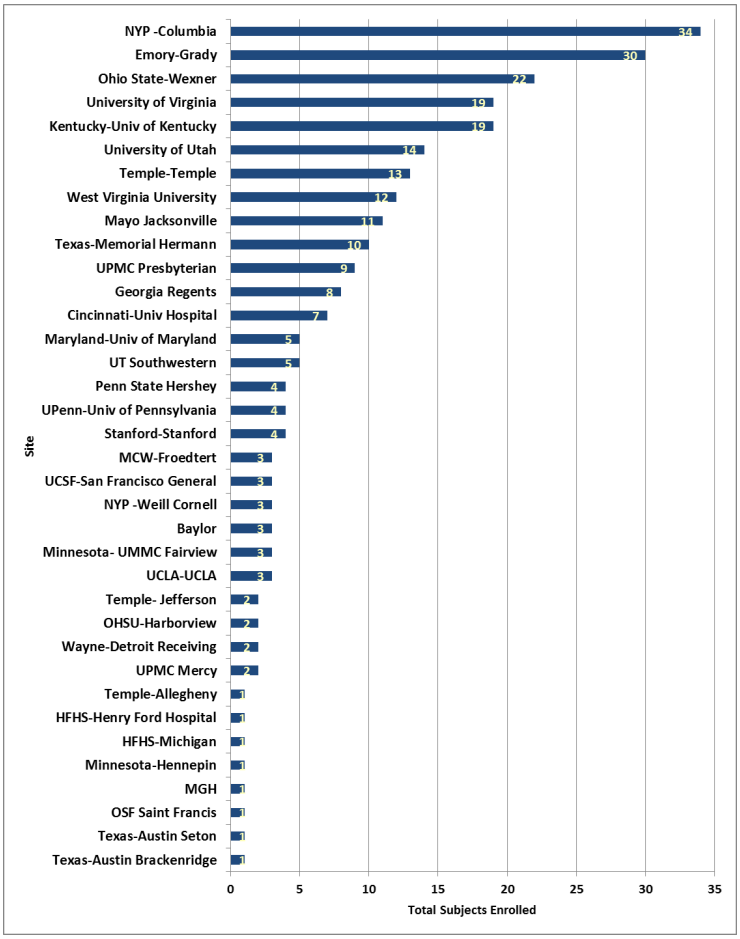
August 2013 was our best month for recruitment to date with 29 total enrollments. Congratulations to all of our SHINE sites for their efforts with site start-up, screening and enrollment to make this trend in increasing recruitment possible. In October, Ohio State's Wexner Medical Center set a record high of 6 enrollments in one month. Kudos to their study team. Special congratulations to the teams at Texas and their spokes, Austin Seton and Austin Brackenridge, as well as OSF St. Francis on their recent first enrollments. Additionally, our thanks to the following recently activated SHINE sites: Lincoln MC, Maimonides MC and University Hospital of Brooklyn (SUNY Downstate); Valley Baptist MC (UT Houston); University of Arizona MC (Arizona); and Summa Akron City (Ohio State).

In the coming months, we welcome your feedback as we work to make the retraining experience more valuable by individualizing and making new resources available. Also, because we have reached a substantial number of subjects that have completed follow up, we will begin to focus on retention and will be including these details in the next quarterly recruitment reports.

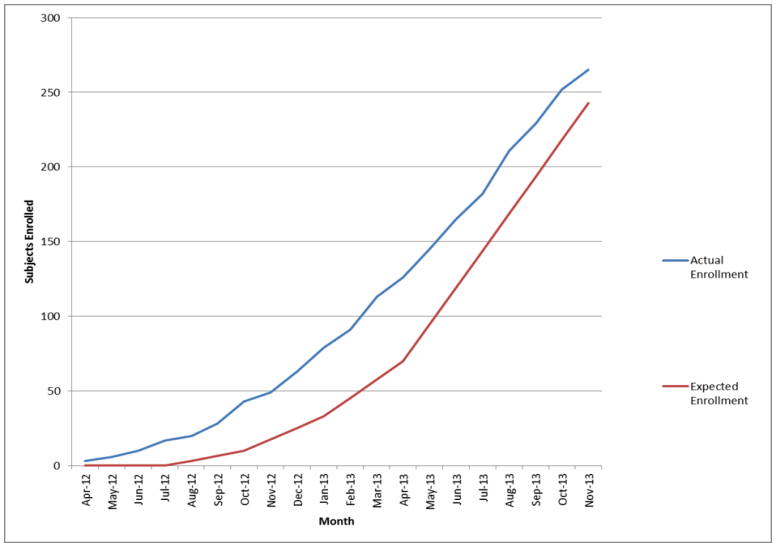
Thanks for all that you do to support the SHINE trial.

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

SHINE Recruitment—Apr 2012-Nov 2013



SHINE Enrollment by Site—Nov 2013



Introducing the NYP Columbia SHINE Team

A big **THANK YOU** to the team at Columbia University Medical Center for their continued efforts to support SHINE. NYP Columbia currently leads SHINE enrollment nationwide.

Dr. Stephan Mayer attributes their recruitment success to their dedicated team and having investigators physically present 24/7. He also says that there is a Gladwellian tipping point after several enrollments where things begin to fall into a routine for the study team and nurses.

Pictured here are several of the nurses that are integral to SHINE trial success as well as the core SHINE team which includes Stephan Mayer, MD, Cristina Falo, PhD, Angela Velazquez, Emma Meyers, Christine Lesch, PharmD, and many other co-investigators.

Tips for CRF Completion

- **Calculating Treatment Days 1-3 and End of Treatment Time**—Day 1 begins at the time of randomization (0-24) hours, Day 2 is 25-48 hours, and Day 3 is 49-72 hours. The treatment period begins at the time of randomization. The End of Treatment visit takes place on the date that the study infusion was stopped.
- **Hypoglycemic Event CRF**—This CRF is only required when the BG is less than 70mg/dL (one per episode <70).
- **Neurological Worsening CRF**—This CRF is only required when the SHINE study definition for Neurological Worsening is met (≥4 point increase in NIHSS that persists for 24 hrs (+/-4hrs)).
- **Hospital Arrival for In-Hospital Strokes**—The date/time of hospital arrival entered on the Eligibility CRF should be the actual date/time of hospital arrival (not the time of symptom onset).
- **Unblinding**—Please remember not to include notes that could unblind in the General Comments section.

Karen Briggs, SHINE Data Manager

INTERNATIONAL STROKE CONFERENCE 2014

Please make plans to join the SHINE leadership team at the Ongoing Clinical Trials Poster Session II on Thursday, February 13, from 6:15-6:45 PM in Hall G. As a reminder, we'll be highlighting sites with recent SHINE recruitment success during this session. We hope to see you there!

Frequently Asked Questions

Q: What are the reasons that a patient who is being considered for SHINE would be excluded due to the inability to obtain a full NIHSS?

A: When it is not possible to obtain a full NIHSS within 30 minutes of the time of randomization, potential candidates must be excluded from SHINE. Categories on the NIHSS may be untestable due to joint fusion or amputation at the proximal joint, intubation, or other barriers to producing speech.

In the case of amputation or joint fusion at the shoulder or hip, motor arm, motor leg, and the limb ataxia assessments are untestable. Note that only amputations or joint fusions at the proximal joint are untestable.

If a patient is intubated or has other physical barriers to producing speech, it is likely not possible to assess dysarthria within 30 minutes of the time of randomization. Also note that it is possible score a comatose patient by using coma scoring instructions.

Q: Do you have any information about how to fill out the Antithrombotic Medications form?

A: While protocols vary by site, the information below briefly describes unfractionated and low molecular weight heparin and provides common dosing regimens for reference.

#12: Unfractionated heparin: full dose anticoagulation – Heparin continuous infusion with dose adjusted to therapeutic PTT.

#13: Unfractionated heparin: DVT prophylaxis – Fixed dose (usually 5,000 units) given subcutaneously twice or three times daily.

#16: LMWH: full dose anticoagulation -weight based dosing of LMWH (ex. Enoxaparin 1mg/kg sq BID).

#17: LMWH: DVT prophylaxis –fixed low dose of LMWH (ex. Enoxaparin 40mg daily or 30mg sq BID).

NOTE: tPA is captured on Form 21-IVtPA and IA Therapy and should not be noted on Form 16-Antithrombotic Medications.

Common Dosing Regimens for LMWH & Factor Xa Inhibitors

	DVT prophylaxis	Full dose anti-coagulation (systemic)
Enoxaparin (Lovenox®)	40mg SQ daily or 30mg SQ q12	1mg/kg SQ q12 or 1.5mg/kg SQ daily
Dalteparin (Fragmin®)	2,500 or 5,000 units SQ daily	150-200 units/kg SQ daily (max 18,000 units)
Fondaparinux (Arixtra®)	2.5mg SQ daily	5-10mg SQ daily

SHINE Training Resources

We are building a library of updated SHINE resources. Please email Katrina van de Bruinhorst (Katrina.vandebruinhorst @utsouthwestern.edu) with any resources that you use at your site or with requests for materials that would be helpful with new team members or retraining.

—Katrina van de Bruinhorst, SHINE Recruitment Specialist

SHINE Actively Enrolling Sites

As of November 2013

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

***indicates site with subject enrollment**

Send us your SHINE pictures!!!

In this issue, we are featuring a photo of the study team from NYP Columbia as one of our leading enrolling sites for SHINE, and below are pictures of some of our SHINE leadership team.

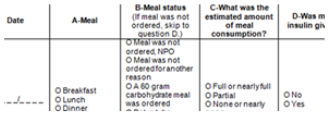
Now we're asking for pictures of your study team—please send to Amy Fansler (acf7h@virginia.edu) as we will start to share the many ways that our SHINE teams are succeeding and exceeding expectations.

Pictured: Joy Pinkerton, Arthi Ramakrishnan, Donna Harsh, Askiel Bruno, Catherine Dillon , Hannah Reimer, Amy Fansler, Katrina van de Bruinhorst, Carol Van Huysen , Karen Briggs, Valerie Durkalski, Angela Pauls, Bill Barsan, Karen C. Johnston, Scott Janis, Chris Hall

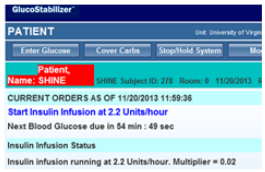
Intervention Group Meals (PO Diet) - Steps for Nurses

1. Assess consumption ~ 20 min after start of meal
   - All or nearly all
   - Partial
   - None or nearly none

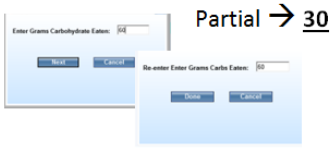
2. Document consumption in EMR or source doc.



3. Click Cover Carbs

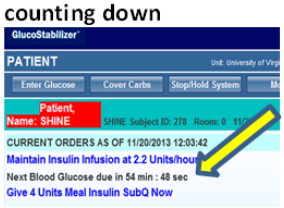


4. Enter carbs eaten (gm)
   All/nearly all → 60
   Partial → 30



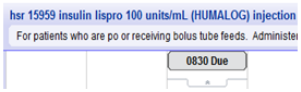
5. Meal insulin dose will display. Enter initials. Click OK.

6. Confirm GlucoStabilizer is counting down



7. Give SQ meal insulin.

8. Chart in medical record.



I-SPOT

Insights on Selected Procoagulation markers and Outcomes in stroke Trial

Total Enrollment: 20
I-SPOT Activated Sites: 41

The lab manual was recently updated and includes information clarifying the timing of the 48 hour blood draw: "At the 48 hour draw, blood should be collected at the time of the scheduled finger stick closest to 48 hours post randomization. If the time of the scheduled finger stick coincides with a meal, the meal should be held until after the scheduled finger stick and blood draw."

Thank you to all sites that are diligently screening SHINE enrollments for inclusion into the I-SPOT sub-study. Please continue to make sure that every eligible I-SPOT patient is enrolled.

—Hannah Reimer, I-SPOT Project Manager

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