

Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

I-SPOT

Nina Gentile, MD
Hannah Reimer



ISPO^T

Insights on Selected Procoagulation markers
and Outcomes in stroke Trial

I-SPOT

- The *I*nsights on *S*electe*d P*rocoagulation markers and *O*utcomes in *S*troke *T*rial (I-SPOT) is an ancillary study to the *S*troke *H*yperglycemia *I*nsulin *N*etwork *E*ffort (SHINE) Trial

I-SPOT

- Will compare blood coagulation factors between SHINE treatment and control patients
- Will determine the relationship between levels of markers of blood coagulation and functional neurological outcome in SHINE treatment and control patients

I-SPOT & SHINE

- I-SPOT nested within the SHINE trial
- Only sites participating in the SHINE trial will be eligible to perform I-SPOT
- Consent for I-SPOT embedded into SHINE consent

Patients eligible for I-SPOT

- A subset of 315 patients enrolled in the SHINE study will be enrolled in the I-SPOT study

I-SPOT INC/EXC

I-SPOT Inclusion Criteria:

- Able to provide a valid informed consent to be in the study (self or their legally accepted representative)

I-SPOT INC/EXC

I-SPOT Exclusion Criteria:

- Anticipated use of systemic anticoagulants
- Known moderate or severe hepatic insufficiency (as defined by INR>1.5 if known or history of variceal bleeding or hepatic encephalopathy)
- Prior or concurrent thrombotic or hypercoagulable condition (Antiphospholipid antibody syndrome; Antithrombin III, Protein C or S deficiencies; Congenital or Inherited Factor deficiencies; Sickle cell disease)

I-SPOT EXCLUSION: SYSTEMIC ANTICOAGULANTS

- IV or IA fibrinolytics
- Warfarin
- IV heparins
- Full dose heparins for known DVT
- Direct thrombin inhibitors
- GIIIB / IIIA inhibitors, or factor Xa inhibitors

Patients on these meds can be enrolled

- SQ DVT prophylactic heparin doses are allowed
- ASA is allowed
- Plavix is allowed

Blood Collection for I-SPOT: WHEN

- Samples drawn at 2 time points
 - Baseline before study drug start and directly after randomization
 - and
 - 48 hours (between 46 and 54 hours)

I-SPOT Blood Collection



- Draw blood samples from a fresh venipuncture
- If it is not possible to draw blood from a fresh venipuncture and is drawn from an existing line, at least 5 ml of blood must be discarded before obtaining samples
- Collect blood through a needle no smaller than 21 gauge
- Use Vacutainer[®] system to collect blood. **DO NOT** drip blood or use syringe to put blood directly into tubes

I-SPOT Blood Collection

- Blood tubes should be filled without use of tourniquet
 - Some procoagulation measures are affected by tourniquet use
 - May use a tourniquet to find the vein then remove as tubes begin to fill
 - If unable to fill tubes without tourniquet present, please mark on the CRF

**FILL BLUE TOP TUBES
COMPLETELY**

**TO ENSURE PROPER RATIO OF BLOOD TO
SODIUM CITRATE**

I-SPOT Blood Collection

- After tubes fill, **gently** invert tubes 4 times to mix blood with sodium citrate
- Blood may be processed immediately after it is drawn and centrifuge start time must be within 60 minutes of collection

Instructions are in rcf (g) NOT rpm

If your centrifuge is in rpm you must convert to rcf (g)

$$\text{RCF (g)} = 1.12 \times \text{Radius} \times (\text{rpm}/1000)^2$$

Helpful sites:

- <http://www.piercenet.com/files/TR0040-Centrifuge-speed.pdf>
- http://insilico.ehu.es/mini_tools/rcf_rpm.php

Check your centrifuge before collecting samples for I-SPOT

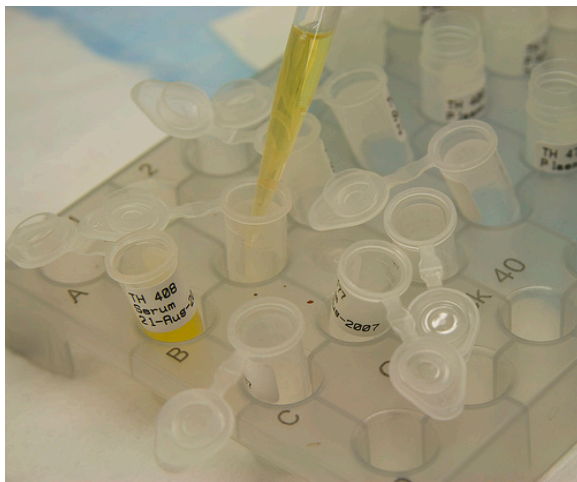
PROCESSING BLOOD

- **BEFORE TUBES GO INTO CENTRIFUGE**, remove 2 ml of whole blood from any of the 3 tubes and divide between 2 cryovials
- Centrifuge remaining 3 tubes of blood at 1500 RCF (g) for 20 minutes
- Fill each of the cryovial tubes with approximately 0.3 ml of plasma
- Care should be taken not to disturb the red cell layer during harvesting of the plasma.
- **BLOOD MAY NOT BE RESPUN**

**BLOOD
MAY NOT
BE RESPUN**

We would rather have mixed or hemolyzed blood than blood being respun!

- Label the cryovial tubes with the SHINE ID number, date and either '*Baseline*' or '*48 hour*'
- Place caps on the cryovial tubes tightly
- Record the number of cryovial tubes on Blood Sample Collection Form, for data entry into WebDCU



Processing Blood

- Put only one one subject's specimens in a single cryovial box
- Place the cryovial tubes into the cardboard cryovial box and, using a permanent marker, label the box with the following information:
 - I-SPOT Study
 - Subject ID#
 - I-code number
 - Date and time blood collected



Storing Blood

- **Place the cardboard cryovial box containing the cryovial tubes into the freezer immediately at - 80°C (-70°C is acceptable) until ready to ship. Make sure the samples are frozen so that the cryovial tubes are upright**
- **Do NOT lay the cryovial tubes on their side**

Storing Blood

- DO NOT take the cardboard cryovial box out of the freezer for the 48 hour samples until you are ready to place the cryovial tubes inside to prevent thawing of the frozen samples

SHIPPING BLOOD SAMPLES

- I-SPOT Coordinating Center will e-mail when the I-SPOT samples should be shipped (within 30 days after an enrollment)
- I-SPOT Coordinating Center will e-mail UPS airbill that will be printed and placed on the outside of the shipping box

Shipping Blood Samples

- **Make sure that the Baseline and 48hr are collected and placed in a single cryovial box for each subject before shipping**

I-SPOT CONTACTS

- Dr. Nina T. Gentile Project Director and
 Principal Investigator
- Dr. A. Koneti Rao Principal Investigator
- Dr. Anamika Singh Laboratory Manager
- Hannah Reimer Project Manager

HOTLINE

For urgent I-SPOT issues please call the
I-SPOT hotline at:

774-23 I-SPOT
(774-234-7768)