Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

Investigator Meeting for New NETT Hubs

November 12, 2012

NIH-NINDS U01 NSO69498

Stroke Hyperglycemia Insulin Network Effort Investigator Meeting Agenda

7:00-8:00am	**BREAKFAST/REGISTRATION**
8:00-8:15	**Opening Remarks** - Barsan/Janis/Johnston
8:15-8:45	**Eligibility** - Johnston
8:45-10:15	**Protocol Training** - Bruno • Review of the basics • Hypoglycemia protocols & pauses • Post protocol & outcomes - Johnston
10:15-10:45	**BREAK**
10:45-11:45	**Study Laptop Training** - Zito
11:45-12:30pm	**Protocol Cases and Q&A** - Johnston
12:30-1:30	**LUNCH**
1:30-2:00	**Randomization and Navigating in WebDCU** - Briggs
2:00-2:45	**Preparing for Site Readiness** • Preparing study orders & laptops - Fansler • Regulatory requirements & RC process - Ramakrishnan • Coordinator panel from enrolling sites - Ewing/Fansler/Hall/Reimer
2:45-3:00	**Safety Reporting** - Dillon
3:00-3:15	**Monitoring** - Frederiksen/Harsh
3:15-3:30	**BREAK**
3:30-3:45	**Recruitment Update** - Hall
3:45-4:15	**I-SPOT** - Gentile/Reimer
4:15	**Adjourn**

Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial

Eligibility

Karen C. Johnston, MD, MSc

Administrative PI

Inclusion Criteria

- Age 18 years or older
- Diagnosis of ischemic stroke (neuroimaging must exclude ICH)
- Treatment must begin w/in 12 hrs of stroke symptom onset and w/in 3 hrs of hospital arrival (protocol change underway, request variation)

Inclusion Criteria

- Known Type II DM & glucose >110 mg/dL OR blood glucose ≥150 mg/dL in pts w/o known diabetes (finger stick at enrolling hospital)
- ☆Baseline NIHSS 3-22 (within 30 min of randomization)
- ☆Pre-stroke mRS of 0 (protocol change underway)
- Valid informed consent

Exclusion Criteria

- Type I DM (hx, records, docs, etc)
- Neurological or psychiatric illness that would confound neurological or outcome assessment (Exclude any pt deemed by enrolling physician to have condition that confounds enrollment neurological exam)
- Received experimental therapy for enrollment stroke. (IV tPA (up to 4.5 hrs), IA tPA &IA therapies including FDA cleared devices allowed. Non FDA cleared devices excluded)

Exclusion Criteria

- Pregnant or breast-feeding
- Other serious conditions that make pt unlikely to survive 90 days
- Inability to follow protocol or return for 90 day f/u
- Renal dialysis

Common Eligibility Questions

Q1: How do we distinguish between Type 1 and Type 2 diabetes when we are trying to determine if a patient meets eligibility criteria to be enrolled?

A1: T1DM vs T2DM

- Based on history provided by patient/family and medical records or physician contact
- Any pt on insulin therapy with no known history of oral agents assumed to be T1
- Ask the following questions
  - Ever tried to control diabetes with diet/exercise only?
  - Ever taken a pill for your diabetes?
  - Since diagnosis always used insulin (shots or pump)?
  - Age when diagnosed?
- Contact the PI on call with questions

T1DM vs T2DM (FAQ info)

<u>Type 1 (also called T1DM, insulin-dependent or juvenile diabetes)</u>

- Commonly is diagnosed from infancy to the late 30s
- Pancreas produces little or no insulin
- Cannot be prevented and no cure
- Causes dependence on injected or pumped insulin for life

<u>Type 2 (also called T2DM, non-insulin-dependent or adult-onset diabetes)</u>

- Most common form of diabetes
- Typically develops after age 40, but can appear earlier
- Body does not produce enough or use insulin effectively
- Treatments include diet, exercise, oral medications

Q2: What do we do when a patient says he has borderline diabetes?

A2: Borderline Diabetes

- Must either have a history of type 2 diabetes and a glucose level of >110mg/dL OR a glucose level of ≥150mg/dL with no known history of diabetes.
- Diagnosis of diabetes based medical history provided by the pt/family and/or the medical record.
- If a pt/family reports a history of borderline diabetes and it is not clear in the medical record, contact the PI on call.

Q3: A potential subject is known to be a type 2 diabetic and is insulin dependent at home. Can we enroll someone who on NPH insulin?

A3: Enrolling Insulin Dependent Diabetic

- Many diabetics will be on home insulin and are eligible
- Special situation – on insulin pump – not an exclusion but up to the discretion of enrolling investigator
- All home DM meds will be held during study treatment

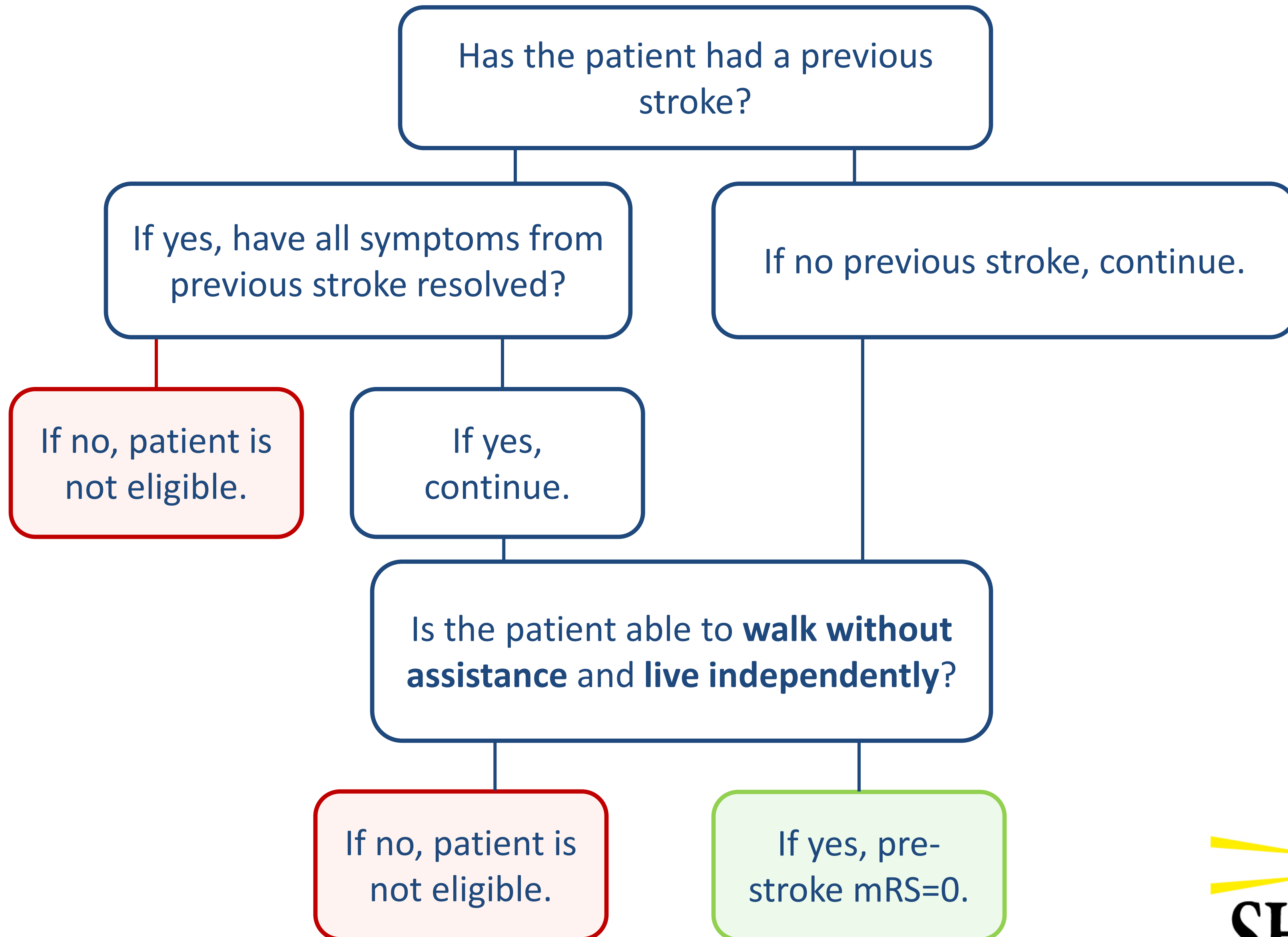
Q4: Can we use the glucose check from the EMS for eligibility?

A4: Eligibility Glucose Check

- No – cannot use OSH or EMS POC result
- Need one POC glucose check (finger stick) at enrolling hospital prior to randomization
- Cannot be a serum glucose level from lab
- Once you have an eligible POC result, you do not have to repeat before randomization
- If another check is done and not in range, pt no longer eligible and should not be randomized
- If BG is below the eligible level but close, you may check again later

Q5: We are screening an 81 y/o man with diabetes who has had a stroke with right sided ataxia. The ataxia completely resolved. He has numbness in both his feet. He lives alone and walks with a cane. How do we score the pre-stroke mRS?

The pre-stroke mRS & eligibility



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A5: Pre-stroke mRS

- mRS = 0
  - Stroke symptoms have resolved
  - His numbness is his diabetic neuropathy
  - He is independent
  - A cane is a necessary device for walking and is not considered assistance

- Sample mRS cases posted on study website
  - May be helpful in training investigators

Q6: Should we enroll a patient with a POC glucose of 451mg/dL in the ED if he meets all of the other eligibility criteria?

A6: Screening a Patient w/ High Glucose

- Should not enroll if pt requires insulin infusion (DKA, hyperosmolar coma, etc)
- Any SHINE patient with BG$\geq$ 500 requires notification of the safety monitor and may be withdrawn from study treatment
- Enrollment of pts with very high glucose is per judgment of investigator/treating team

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