

# Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial Consent/Eligibility/Randomization

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# Identifying Patients

- Usually emergency room
- Could be arrival to ward upon direct transfer from OSH
- Screen all acute ischemic stroke pts with onset within 12 hours and blood glucose  $> 110$
- Spotter concept
- Clearly defined plan for summoning definitive screening team/ enrolling team



# Consent – General Concepts

- Use standard consent procedures per local regulatory
- Written informed consent
- No emergency exemption
- Randomization must occur w/in 3 hours of arrival to enrolling ED (hospital)



# Eligibility Criteria

## Inclusion

- $\geq 18$  yrs of age
- Ischemic stroke – clin dx (ICH excluded by imaging)
- Treatment w/in 3 hours of hospital arrival and 12 hours after stroke symptom onset. (Treatment start time is randomization time). Last known well for unknown.
- Known Type II DM and glucose  $>110$  mg/dL OR no known DM and admission gluc  $\geq 150$  mg/dL



# Eligibility Criteria

## Inclusion

- NIHSS 3-22 (inclusive)
- Pre-stroke mRS=0
  - Scoring tips:
    - Previous stroke
    - Non-previous stroke
- Valid informed consent



# Eligibility Criteria

## Exclusion

- Type I DM
- Pre-existing Neuro or Psych illness that confounds
- Experimental therapy for the enrollment stroke (IV tPA up to 4.5 hrs allowed), (IA therapies including use of FDA cleared devices allowed), (non FDA cleared devices NOT allowed)
  
- Pregnant or breast feeding
- Unlikely to survive to 90 days
- Unable to follow protocol or f/u
- Renal dialysis



# Randomization– General Concepts

- Web DCU based randomization
- Randomization time is start of treatment time
- Must be randomized within 12 hours of symptom onset and 3 hrs of arrival to enrolling hospital
  
- RAR – Response Adaptive Randomization
- Start out 1:1 (flip of coin)
- RAR – higher chance of being enrolled in whichever treatment group has better outcomes

