

Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial Outcome Assessment

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Summary - Clinical Outcomes

- Primary Study Outcome – 3 month mRS
- Primary Safety Outcome – frequency of severe hypoglycemia (<40 mg/dL) in intervention group versus control group
- Additional Outcomes
 - 6 week phone call – mRS by phone, SAEs
 - 3 month - BI, NIHSS, QOL



Outcome Visits

- 6 week visit – by phone
 - mRS and SAE
- 3 month visit – in person
 - mRS, NIHSS, BI, QOL
 - SAEs
 - Unblinding survey (patient and investigator)
- mRS both visits – blinded investigator
 - Must be blinded to treatment



