

Updated FAQ's based on PI line calls

Screening

Q1. We are screening a patient who has a history of cancer which has spread and he is scheduled to undergo chemotherapy. Can we still enroll in SHINE?

A1. You will need to inquire with the patient's oncologist and call the PI hotline. The oncologist must confirm that the patient's 90-day prognosis is good without any major side effects. The PI on call will have to confirm eligibility.

Q2. We are screening a patient who had a glucose of >400 and was given 7 units of regular insulin 4.5 hours ago. The glucose is now 250. Is this patient still eligible?

A2. Yes. Generally speaking, 4.5 hours is enough time elapsed to examine the peak effect of regular insulin (2-4 hours). Sites should use their clinical judgment and call the PI hotline with any questions during the screening period.

Q3. We have a patient whose glucose is very high (>400). The treatment team wants to put him on an insulin drip. What should we do?

A3. Coordinators/local site investigators should call the PI line to discuss specific cases such as these. Depending on the case, the SHINE PI's will make a recommendation whether to enroll or not.

Intervention

Q1. Our patient has blown both PIV's she had and is a very difficult stick. What should we do to deliver the IV insulin?

A1. You need a dedicated port for the study treatment. Using a central line is fine as long as you have one of the ports dedicated to insulin only.

Q2. Our patient became hypoglycemic to 49 and we did not get a confirmatory serum blood glucose prior to dosing with D50. Should we get it now?

A2. No. This is a protocol violation but it is much more important to treat the hypoglycemia as soon as possible. Do not ever delay the administration of D50 in order to get the serum glucose sample.

Q3. Our patient was initially randomized with a stroke scale of 4. He was given tPA, then found to have a hemorrhagic conversion on day 1. His NIHSS remains a 4 or 5 and his repeat scan shows no mass effect. Should we stop the intervention and follow up for outcome only?

A3. No. Hemorrhagic conversions without mass effect that do not account for neurological worsening are not reasons to stop the intervention or not to enroll. Please call the PI hotline if there is any question about conversions.