

Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial Pharmacy and Blinding

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Treatment assignment

- Randomization generated by study team in WebDCU
- Study team provides hard copy of treatment assignment to pharmacy



Study treatment by group

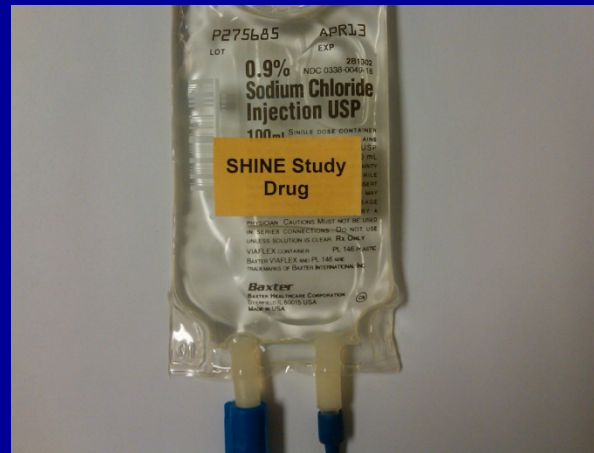
	Control Group	Intervention Group
IV Infusion	Normal saline 0.9% Sodium Chloride	Human regular insulin Humulin R, Novolin R
Subcutaneous Injections	Human regular insulin Humulin R, Novolin R AND Basal insulin (Level 3 only) glargine (Lantus)	Rapid acting analog insulin lispro (Humalog), aspart (Novolog) or glulisine (Apidra) OR Normal saline 0.9% Sodium Chloride



Control group – Study treatment

Control Group

IV infusion
Normal saline
Per sliding scale (continuous)



Subcutaneous injections

Human regular insulin
Per sliding scale (@ 06:00, 12:00,
18:00 & 24:00)



AND

Basal insulin (Level 3 only)
40% of insulin requirement during
previous 24 hrs (@ ~48 hrs)



Intervention group – Study treatment

Intervention Group

IV infusion

Human regular insulin (1:1)
Per GlucoStabilizer (continuous)



Subcutaneous injections

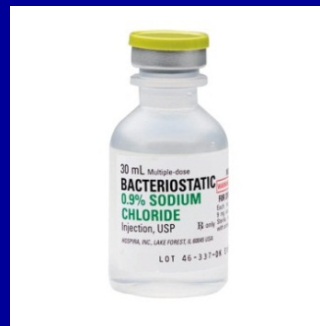
Rapid acting analog insulin
(meal insulin)

Per GlucoStabilizer @ ~06:00,
12:00 & 18:00

OR

Normal saline

0.05 mL @ ~09:00 & 21:00



Dextrose 50% in Water (D50)

- D50 stored to allow immediate availability
- Glucose $<80\text{mg/dL}$ →
 - Control group - 25 ml (1/2 amp)
 - Intervention group - individualized dose per GlucoStabilizer



Control screens – Orange background

SHINE Trial Portal

Click Here
for
Control Group

SHINE Trial

User ID:

Password:

LOG IN

SHINE Subject ID:

Please enter values

Date:

Time:

Glucose (mg/dL):

SubQ Insulin (Units):

Saline Drip (mL/hr):

Basal Insulin (Glargine) (Units):

D50 (mL):

Notes:

Next

Cancel

Check finger stick

IV Saline

Start at rate indicated below and adjust if indicated each time glucose is checked.

Start at Level 2 if glucose is >450 mg/dL.

mL/hr	Glucose (mg/dL)	Level 1 Insulin dose (units)	Level 2 Insulin dose (units)	Level 3 One time sq basal insulin (Glargine) and continue Level 2 Insulin dose (units)
5	>450	8	16	16
5	400-450	7	14	14
5	351-399	6	12	12
5	300-350	5	10	10
5	251-299	4	8	8
5	200-250	3	6	6
5	180-199	2	4	4
4	80-179	0	0	0
0	<80	See hypoglycemia protocol (Click Here)		

SHINE Subject ID: 5678

New Event

Remove

Hide Protocol

Logged in: shine | Unit: University of Virginia | Tools | Lock Program | Log Out

SHINE Study Drug



Intervention screens – Blue background

Enter BG:

Please check new order

Decrease Insulin Infusion from 2.9 to 1.9 Units/hour
Next Blood Glucose due in 55 min

Entered BG:
Nurse initials (Order Entry):
Administered Insulin Infusion Rate:
Nurse initials (Administered):
Comments:

SHINE Trial Portal

GlucoStabilizer™
INSULIN DOSING SOFTWARE

User ID:
Password:

Click Here
for
Intervention
Group



GlucoStabilizer™

PATIENT Unit: University of Virginia [Log Out](#)

12/30/2011

Insulin Dose = (Blood Glucose - 60) x Multiplier



Maintaining the blind

- IV infusion pumps
- Subcutaneous injections
- Study drug label
- Study laptops



Site pharmacy plan

- Establish site-specific pharmacy plan prior to initiation
- Retain one empty infusion bag for each study patient for monitoring



