

# Stroke Hyperglycemia Insulin Network Effort (SHINE) Trial Treatment Protocols

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Protocol PI



# SHINE Synopsis

- Acute ischemic stroke <12 hrs (onset) and <3 hrs (arrival)
- Baseline blood glucose
  - >110 mg/dL if a known diabetic (type 2)
  - $\geq$  150 mg/dL if not a known diabetic
- Baseline NIHSS 3-22
- Randomized, initially single blind – final outcome double blind – N=1400
  - Control group: SQ insulin only (glu range 80-180 mg/dL) x 72 hrs
  - Intervention group: Sq insulin with meals and IV insulin drip (glu target 80-130 mg/dL) x 72 hrs
- Final outcome - 3 month mRS



# SHINE Synopsis

	Control	Intervention
SQ injections	√	√
IV drip	√	√



# Treatment Groups General Concepts

## Control

- BG range 80-180 mg/dL
- SQ insulin (regular human) per sliding scale
- IV saline drip (to mimic IV insulin drip to maintain blind)
- Q1 hr glucose checks for 1<sup>st</sup> 4 hrs only
- Q3 hr glucose checks after that – but insulin given only at 06:00, 12:00, 18:00 and 24:00 if indicated
- Basal insulin (slow acting) only at 48 hrs if indicated



# Treatment Groups General Concepts

## Intervention

- BG target 80-130 mg/dL
- Glucose checks and IV insulin (regular human) drip adjustments per GlucoStabilizer (computer decision support tool)
- When not eating, SQ saline (to mimic SQ insulin to maintain blind)
- When eating, SQ meal insulin (rapid acting analog) per meal carbohydrate intake



# Detailed Look at Control Group

- Initiation of Treatment
  - Notify pharmacy
  - Start SHINE laptop and click on Control Group
  - Re-check glucose when IV saline is ready
  - Start IV saline infusion per protocol (on screen) and adjust as needed with each glucose check
  - Check glucose q 1hr x4, then q 3hr
  - Give insulin per sliding scale at 06:00, 12:00, 18:00 and 24:00
- Control Group Computer Screen



# Getting Started

SHINE Trial Portal

Click Here  
for  
Control Group

Click Here  
for  
Intervention  
Group

# Control Group Computer Screen

Check finger stick glucose Q 1 hr for the first 4 hours, then Q 3hrs (3:00, 6:00, 9:00, 12:00, 15:00, 18:00, 21:00, and 24:00),  
but give sq insulin if indicated only 4/day (6:00, 12:00, 18:00, and 24:00)

IV Saline	SQ Human Regular Insulin (Humulin R or Novolin R) Sliding Scale			
Start at rate indicated below and adjust if indicated each time glucose is checked.	Start at Level 1. If at the end of the first 24 hours, the previous two glucose levels remain $\geq 180$ mg/dL, advance to Level 2. If after 24 hours on Level 2, the previous two glucose levels remain $\geq 180$ mg/dL, proceed to Level 3. In Level 3, give a one-time subcutaneous basal insulin injection (Glargine) at a dose equal to 40% of previous day's entire insulin dose and continue Level 2 insulin dose.			
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 ( <a href="#">Click Here</a> )		



# Control Group Documenting

**Please enter values**

Date:	<input type="text" value="12/09/2011"/>
Time:	<input type="text" value="06:00"/>
Glucose (mg/dL):	<input type="text" value="185"/>
SubQ Insulin (Units):	<input type="text" value="2"/>
Saline Drip (mL/hr):	<input type="text" value="5"/>
Basal Insulin (Glargine) (Units):	<input type="text" value="0"/>
D50 (mL):	<input type="text" value="0"/>
Notes:	<input type="text"/>

# Detailed Look at Control Group

- Continuation of Treatment
  - Check glucose on schedule
  - Give SQ insulin only at the designated times, if indicated by the sliding scale ( $\geq 180$  mg/dL); 1<sup>st</sup> 24 hrs SQ insulin scale Level is 1
  - Adjust IV saline rate if indicated after each glucose check
  - Same procedure whether eating or not
- Control Group Computer Screen



# Control Group Computer Screen

Check finger stick glucose Q 1 hr for the first 4 hours, then Q 3hrs (3:00, 6:00, 9:00, 12:00, 15:00, 18:00, 21:00, and 24:00),  
but give sq insulin if indicated only 4/day (6:00, 12:00, 18:00, and 24:00)

IV Saline	SQ Human Regular Insulin (Humulin R or Novolin R) Sliding Scale			
Start at rate indicated below and adjust if indicated each time glucose is checked.	Start at Level 1. If at the end of the first 24 hours, the previous two glucose levels remain $\geq 180$ mg/dL, advance to Level 2. If after 24 hours on Level 2, the previous two glucose levels remain $\geq 180$ mg/dL, proceed to Level 3. In Level 3, give a one-time subcutaneous basal insulin injection (Glargine) at a dose equal to 40% of previous day's entire insulin dose and continue Level 2 insulin dose.			
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5	200-250	3	6	6
5	180-199	2	4	4
4	80-179	0	0	0
0	<80	See hypoglycemia protocol ( <a href="#">Click Here</a> )		

# SHINE Allowed Insulins

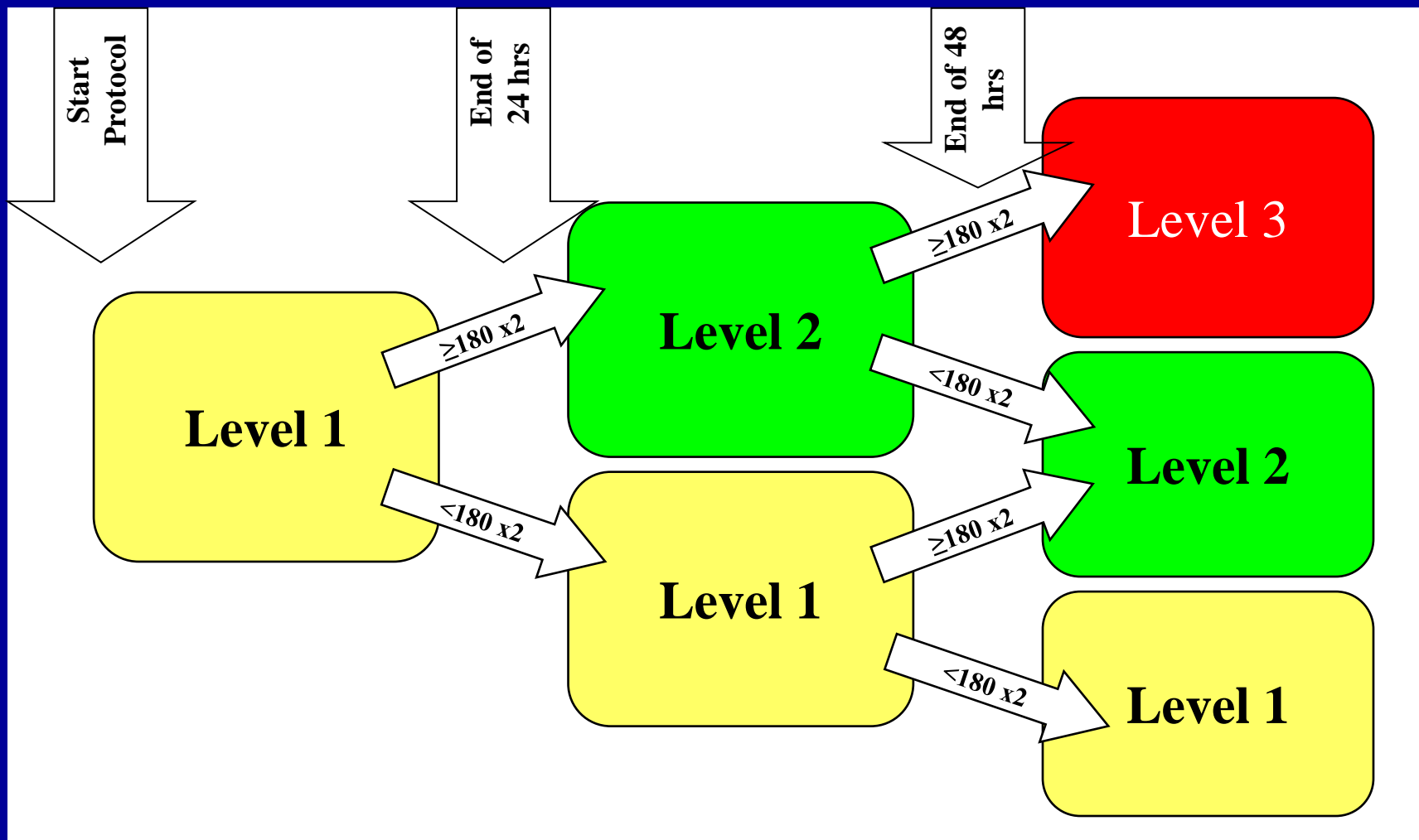
Insulin Treatment Type	Control	Intervention
SQ sliding scale	Regular human: Humulin R, Novolin R	Not Allowed
SQ basal	Slow acting: glargine (Lantus) ONLY	Not Allowed
SQ meal	Not Allowed	Rapid acting analog: humalog (Lispro), novolog (Aspart), glulisine (Apidra)
IV	Not Allowed	Regular human: Humulin R, Novolin R
Insulin syringes	Yes	Yes
Insulin pens	NO	NO

# Sliding Scale Insulin Level Changes

- All patients on level 1 for first 24 hours
- At end of 1<sup>st</sup> 24 hrs (any time of day) advance to Level 2 only if the latest 2 glucose levels  $\geq 180$  mg/dL; otherwise stay on Level 1
- At end of 48 hrs (any time of day) advance to next level (2 or 3) only if the latest 2 glucose levels  $\geq 180$  mg/dL; otherwise stay on current Level
- Level 3 involves SQ basal, slow acting, insulin (Lantus) given once at end of 48 hrs, and the sliding scale insulin doses for Level 3 are the same as Level 2
- Advance level only if indicated at end of 24 and 48 hrs



# Sliding Scale Insulin Level Changes



# Level 3 Control Treatment

## Basal Insulin

- Level 3 is different - only one with basal insulin
- Calculating basal insulin dose - add up all the insulin units given in the previous 24 hrs (25th to end of 48th hr period) available in the SHINE computer; 40% of that total is the dose of basal insulin ( $\times 0.4$ ) to be given once at end of 48 hrs; use only glargine (Lantus) insulin for this
- After the one dose of SQ basal insulin – continue SQ sliding scale insulin Level 3 (the same as Level 2 sliding scale)



# Control Group - Meals

- 60 gram carbohydrate diet should be ordered
- NO estimate of meal consumption required and NO meal insulin given in control group (only SQ sliding scale insulin at 06:00, 12:00, 18:00 and 24:00 if indicated)
- Pts should eat only after their glucose check and the SQ insulin has been given as needed at 6:00, 12:00, and 18:00. (If meal arrives before these times, hold until one of these specified times.)
- Remember not to provide extra meals or any between meal snacks during the 72 hr SHINE treatment protocol.





# Data Entry

- Standard chart documentation
- All glucose/insulin data entry in GlucoStabilizer  
(details discussed in afternoon session)



# Detailed Look at Intervention Group

- Initiation of Treatment
  - Notify pharmacy
  - Start SHINE laptop and click Intervention Group
  - Re-check glucose when IV solution is ready
  - Start IV insulin infusion per GlucoStabilizer recs
- Intervention Group Computer Screen



# Getting Started

## SHINE Trial Portal

[Click Here  
for  
Control Group](#)

[Click Here  
for  
Intervention  
Group](#)

# Intervention Group Computer Screen

**Please check new order**

**Start Insulin Infusion at 2.3 Units/hour**  
Next Blood Glucose due in 55 min

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Entered BG: 175  
Nurse initials (Order Entry):

Administered Insulin Infusion Rate: 2.3  
Nurse initials (Administered):

Comments:

# Detailed Look at Intervention Group

- Continuation of Treatment
  - Recheck and enter glucose in GlucoStabilizer
  - Adjust IV insulin drip per GlucoStabilizer recs
  - When patient is not eating give SQ saline 0.05 cc at ~9 a.m. and ~9 p.m. after glucose checks, to simulate the 0-4 SQ insulin injections in the control group
  - When patient is eating give meal insulin per protocol



# Intervention Group Meals

- Breakfast, Lunch, Dinner – opportunity for meal insulin
- When patient cleared to eat order 60g carbohydrate diet
- Allow 20 minutes from start of eating – then estimate the proportion of meal that was consumed



# Intervention Group

## SQ Meal Insulin Dosing

- Meal consumed – all or nearly all
  - Enter **60** carb meal into GlucoStabilizer
  - Give dose of meal insulin recommended
- Meal consumed– none or nearly none
  - DO NOT make an entry into GlucoStabilizer
  - Give NO meal insulin
- Meal consumed– in between
  - Enter **30** carb meal into GlucoStabilizer
  - Give dose of meal insulin recommended
- NO extra meals during 1<sup>st</sup> 72 hrs



# Intervention Group Meal Insulin Computer Screens

**GlucoStabilizer™**

**PATIENT** Unit: University of Virginia

**Patient, Name: SHINE** SHINE Subject ID: 2468 Room: 0 12/19/2011 Run #: 17 DOB: 01/

**CURRENT ORDERS AS OF Dec 20 2011 12:10AM**

**Start Insulin Infusion at 1.3 Units/hour**

Next Blood Glucose due in 52 min : 55 sec

**Insulin Infusion Status**

Insulin infusion running at 1.3 Units/hour. Multiplier = 0.02

Next Blood Glucose due at 12/20/2011 01:05:37

Last BG = 125

Target BG Range = 80 - 130

Carb Ratio = 10

Enter Grams Carbohydrate Eaten:





# Glucose/Insulin Data Entry

- Standard chart documentation
- All glucose/insulin data entry in GlucoStabilizer (discussed in afternoon session in detail)



# Additional Special Situations

## Reviewed in next session

- Hypoglycemia protocol
- How to sync glucose checks in control group
- Protocol pauses
- Tube feeds
- Early discharge
- Discontinuation of protocol treatment

