

-
Participant ID

Nickname

RISE **CLAMP.2**

Sept 2015

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Restoring Insulin Secretion Study CLAMP: Hyperglycemic Clamp

1. Study Visit Number VISIT	<input type="text"/> BAS <input type="text"/> M12 <input type="text"/> M15
2. Visit date (mm/dd/yyyy) Replaced with DAYSRAND	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
3. Staff ID	<input type="text"/> <input type="text"/> <input type="text"/>

Instructions: Complete this form at any visit when a clamp is completed (BAS, M12, M15).

Prestudy YSI QC (round to the nearest whole number, if applicable)

4. Glucose value of standard 1 (200 mg/dl) **CLQC10** mg/dl

Test Qualification

Confirm the participant's readiness for the clamp:

- | | | |
|---|---|--|
| a. Did not take any study medications the morning of this visit | <input type="checkbox"/> True | <input type="checkbox"/> False |
| b. If any non-study medications were taken this morning, please list: _____ | | |
| c. No current illness | <input type="checkbox"/> True | <input type="checkbox"/> False |
| d. Did not exercise, other than walk, within past 10 hours | <input type="checkbox"/> True | <input type="checkbox"/> False |
| e. Has fasted for at least 10 hours | <input type="checkbox"/> True | <input type="checkbox"/> False |
| f. Recent Hb or Hct within local guidelines to proceed | <input type="checkbox"/> True | <input type="checkbox"/> False |
| 5. Is the participant prepared for the clamp test?
→ All above must be true. CLPREP | <input type="checkbox"/> ¹ Yes | <input type="checkbox"/> ² No |

→ If YES, Proceed. If NO, STOP and reschedule the clamp test.

- | | |
|--|---|
| 6. If menstruating, date of last menstrual period (leave blank for males) (mm/dd/yyyy) | <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> |
| 7. Weight (kg) WEIGHT | <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> kg |
| 8. -10 min fasting bedside glucose CLFASTCGLM10 | <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mg/dl |
| 9. -5 min fasting bedside glucose CLFASTCGLM5 | <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> mg/dl |
| 10. Stage 1 D20W glucose bolus CLBOLUST | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ml |

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Glucose Measurements

→ A small volume of arterialized venous blood will be obtained at 5-minute intervals throughout the clamp for measurement of plasma glucose concentration and titration of the dextrose infusion.

Target Time	(a) Timer time	(b) Bedside Glucose (mg/dl)	(c) Infusion Rate (ml/hr)
0 minute → Start timer now	<input type="text"/> 0 <input type="text"/> 0 <input type="text"/> 0 . <input type="text"/> 0 <input type="text"/> 0		
11. 30 minutes	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> CLATIME30M/CLATIME30S	<input type="text"/> <input type="text"/> <input type="text"/> CLAGLUC30	<input type="text"/> <input type="text"/> <input type="text"/> CLAINF30
12. 60 minutes	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> CLATIME60M/CLATIME60S	<input type="text"/> <input type="text"/> <input type="text"/> CLAGLUC60	<input type="text"/> <input type="text"/> <input type="text"/> CLAINF60
13. 90 minutes	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> CLATIME90M/CLATIME90S	<input type="text"/> <input type="text"/> <input type="text"/> CLAGLUC90	<input type="text"/> <input type="text"/> <input type="text"/> CLAINF90
→ Start 'Steady State' Sampling			
14. 100 minutes*	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> CLATIME100M/CLATIME100S	<input type="text"/> <input type="text"/> <input type="text"/> CLAGLUC100	<input type="text"/> <input type="text"/> <input type="text"/> CLAINF100
*If target plasma glucose of 200 ± 10 mg/dl is not achieved by 100 minutes, delay 'Steady State' sampling and continue adjusting the glucose infusion to achieve this target. In all cases Steady State sampling must be started by 120 minutes on the timer. See MOP v. 2 Chapter 5 for further details.			
15. 1 st sample (e.g. 110 minutes)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> CLATIME110M/CLATIME110S	<input type="text"/> <input type="text"/> <input type="text"/> CLAGLUC110	<input type="text"/> <input type="text"/> <input type="text"/> CLAINF110
16. 2 nd sample (e.g. 120 minutes)	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> CLATIME120M/CLATIME120S	<input type="text"/> <input type="text"/> <input type="text"/> CLAGLUC120	<input type="text"/> <input type="text"/> <input type="text"/> CLAINF120
17. URINE Volume at end STAGE 1 (measure total urine volume and collect 2 ml sample for CBL analysis)		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ml CLURINE	
→ Restart timer at start of Phase 2 of the clamp.			
18. Stage 2 D20W glucose bolus * If less than the amount calculated by the spreadsheet, enter reason in Q23 below.		<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> ml CLBOLUS2	
19. Was the Stage 2 D50W glucose bolus required (50 ml)? CLD50BOLUS * Required if 15 minute glucose of Stage 2 is less than 400 mg/dl		<input type="text"/> 1 Yes <input type="text"/> 2 No	
a. Stage 2 D50W glucose bolus * If less than 50ml, enter reason in Q23 below.		<input type="text"/> <input type="text"/> ml CLD50BOLAMT	

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*If target plasma glucose of >450 mg/dl is not achieved within 30 minutes of the start of the second phase, delay 'arginine injection' sampling and continue adjusting the glucose infusion to achieve this target. In all cases arginine infusion must be started by 45 minutes. Reset timer when arginine infusion begins. See MOP v. 2 Chapter 5 for further details.

22. The Hyperglycemic Clamp was (CHECK ONLY ONE): **C**PROBLEM

Completed without problem	1
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Completed with a problem	2
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Not completed	3
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23. If “**not completed**” or “completed **with** a problem,” including but not limited to issues with glucose bolus delivery, please provide complete information describing the problems or variances from the usual procedure. **CLWHY**

[illegible]