



Standard Operating Procedures Clinical and *Translational Research Center*

Title:	Frequently Sampled Intravenous Glucose Tolerance Test (FSIVGTT)		
Approved By:	<i>Christina Wang MD</i>	Effective Date:	March 19, 2012
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Purpose: The CTSC nurse will provide care in a manner which ensures the delivery of safe, competent, effective clinical research subject care which is consistent with the policies and procedures of Clinical and Translational Science Institute.

The research professional nurse will assume responsibility and accountability for promoting interdisciplinary collaboration with the Principal Investigator and his/her research staff as well as for the careful, precise performance of the FSIVGTT in accordance with the study protocol.

I. POLICY

1. FSIVGTT procedures will be performed by CTSC nurses who have been certified in the performance of IV procedures.
2. Subjects must have been NPO for 12 hours prior to the procedure except for water.
3. A study physician must sign medical orders prior to the start of the procedure.

4. Notify the Investigational Pharmacist when the visit is booked, with the subject's age, study ID number, IRB number and name.
5. On the morning of the visit weigh and measure the height of subject and notify the Investigational Pharmacist of same. She/he will prepare the intravenous infusions of 25% glucose and the insulin solution.
6. Subjects must be appropriately consented, with the consenting process appropriately documented in the chart.
7. Have orange juice and/or glucose tablets and 50% Dextrose for IV infusion available for use if necessary.
8. Have the subject's source documents and a procedure tracking form (refer to attached sample) ready prior to beginning the procedure.
9. Have a second research nurse available for the period of the procedure that includes the glucose and insulin infusions.
10. Perform urine pregnancy test on all female subjects.

II. PROCEDURE

A. Morning of the procedure:

1. Set up two IVs of 250 ml Normal Saline with primary tubing attached to two stopcocks and extension tubing with a clamp, one for each arm (refer to attached list of required supplies for an FSIVGTT).
2. Confirm overnight fast.
3. Weigh subject and record height; notify Investigational Pharmacist of measurements.
4. Apply disposable hot packs to both arms prn.
5. Have subject void prior to starting IVs; perform Quik-Vue urine pregnancy test on female subjects.
6. Measure and record vital signs.

7. Start IV "A" in right arm and record time. Attach 250 ml bag of NS to IV and run at TKO rate.
8. Measure fasting blood sugar from venous sample from IV "A" prior to continuing with study; if FBS is 65 mg/dl or less, inform P.I. and do not proceed with FSIVGTT.
9. Start IV "B" in left arm and record time. Attach 250 ml bag of NS to IV and run at TKO rate.
10. Wait 30 minutes after the start of IV "B" prior to the baseline draw.
11. Designate one IV as the one for blood draws; the other arm is designated for use for the glucose and insulin administration only.
12. Ensure that all vacutainer tubes are on ice in a plastic tub or graduate container; use a second container of ice for tubes of blood after they have been drawn and gently agitated.
13. All blood draws are performed from one IV, using a one syringe/one vacutainer holder technique from the outside ports of the two stopcocks. Attach one sterile 3 cc syringe to the distal stopcock and one vacutainer holder with luer lock adapter attached to the proximal stopcock.
14. Follow the same procedure for each blood draw from the sampling arm: At 10-15 seconds before the assigned sampling time, close the distal stopcock to the IV, withdraw 1-2 ml of saline and blood into the distal syringe (to clear the line), then close the proximal stopcock to the IV, and **exactly at the minute mark**, draw the required amount of blood into the required chilled vacutainer tube (via the vacutainer holder attached to the stopcock), close the proximal stopcock, remove the vacutainer holder/luer lock adapter, gently agitate the tube of blood and place the specimen on ice. Quickly return the 'discard' blood/saline to the patient via the distal stopcock and open the stopcock again to the IV. Using a sterile cotton tipped applicator, clean out the proximal stopcock connection where the sample was drawn and quickly add a new sterile luer adapter attached to a clean vacutainer holder to use for the next blood draw.
15. Set the digital timer to the countdown ("down") mode at the -15 minute time point, or other time point as specified in the protocol.

16. Draw the remaining minus time points at the times specified in the protocol.
17. At minute 0 (baseline), administer the Dextrose 25% solution via the IV in the non-sampling arm over the exact period of time specified in the protocol; administer at a slower rate **and make a notation on the tracking form** if administering the glucose rapidly will injure the vein and/or if the subject complains of discomfort at the IV site. Following the administration of the Dextrose, remove the proximal stopcock, using sterile technique, and re-attach the unused stopcock to the clave (to prevent contamination with Dextrose when the subsequent infusion of Insulin is given).
18. At minute 0 (baseline), change the digital timer to run in the 'up' mode---from the time of the Dextrose administration.
19. Draw the samples, per protocol, from the sampling IV at the intervals specified in the protocol (in adults, often at +2", +3", +4", +5", +6", +8", +10", +14" and +19", sometimes less frequently in children)
20. At minute +10, administer the Insulin Infusion prepared by the Investigational Pharmacist into the proximal stopcock of the IV in the non-sampling arm over the exact period of time specified in the protocol, usually over one minute.
21. Flush the line with NS following the administration of insulin.
22. Draw the samples, per protocol, from the sampling IV at the time points specified in the protocol, usually at +22", +25", +30", +40+50". +70", +100", +140", and +180"(may be less frequently in children).
23. If the sampling IV becomes non-functional at any time following administration of the Dextrose and Insulin during the test switch arms and utilize the other IV for the remainder of the blood draws. **Be certain that both stopcocks have been replaced with sterile ones so that blood draws are not contaminated with glucose or insulin.**
24. Try not to discontinue this IV, however, in case it needs to be converted to the sampling IV arm during the remainder of the test.
24. At each blood draw check carefully for evidence of clot formation in the distal stopcock on the sampling IV. If any evidence of a clot

is found, remove the syringe, clean out the port with a sterile cotton tipped applicator and attach a new sterile 3ml syringe. Flush the port with NS prn to maintain patency if the NS drip is inadequate.

25. If the subject needs to ambulate to the bathroom during the procedure, ensure that the trip occurs at an appropriate time during the sampling, i.e., not during the every one minute blood draws. Both IVs can be maintained with a saline lock and then re-attached to the NS IV tubing when the subject returns to the testing area.
26. Take a final set of vital signs and record.
27. Perform a final blood glucose test with a glucometer prior to discontinuing the IV's and prn at any time the subject develops any signs or symptoms of hypoglycemia.
28. Notify MD if subject develops hypoglycemia.
29. DC both IVs. Apply Polysporin, sterile 2X2's and pressure dressings with Coban to both IV sites with instructions to the subject that the dressings can be removed after 30 minutes.
30. Provide the subject with a meal ticket, parking pass and/or any materials pertinent to the study.

References:

Appendices: