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Procedures for Performing the Mixed-Meal Tolerance Test (Appendix 2 of "Safety and Efficacy of Imatinib for Preserving Beta-Cell Function in New-onset Type 1 Diabetes Mellitus")

In 1 collection

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ABSTRACT

This is Appendix 2 of "Safety and Efficacy of Imatinib for Preserving Beta-Cell Function in New-Onset Type 1 Diabetes Mellitus".

This clinical study is supported by JDRF. The aim of the collection is to determine whether imatinib will slow the progression of the autoimmune destruction of ß cells and lead to the preservation of C-peptide secretion in T1DM and to assess Diabetes-related objectives and safety of Imatinib in participants with new-onset type 1 diabetes mellitus".

ATTACHMENTS

dngubkeaf.pdf

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COLLECTIONS

Collection of Protocols and Guidelines for Safety and Efficacy of Imatinib for Preserving Beta-cell Function in New-onset Type 1 Diabetes Mellitus

KEYWORDS

Safety, Efficacy, Imatinib, Beta-cell function, New-onset Type 1 Diabetes Mellitus

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GUIDELINES

The mixed-meal tolerance test (MMTT) is performed in the morning (between 7:00 a.m. and 10:00 a.m.), which means that administration must begin within this time. It is recommended that the tests be scheduled early in the morning (7:00–7:30 am) because blood glucose will be more likely to be within the target range at that time.

The mixed meal used in this protocol will be the Boost® High Protein Nutritional Drink (Nestlé Nutrition). If a participant has a known food allergy to one or more components of Boost, an equivalent substitution may be used. The MMTT should take 250 minutes to perform.

Dietary Guidelines and Pretest Instructions

Carbohydrates (CHO) should not be restricted from the diet before the test. A general guideline is that preadolescent participants should consume at least 25 kcal (6.25 g) CHO/kg/day and adolescent and adult participants should consume at least 15 kcal (3.75 g) CHO/kg/day for 3 days before the test. These are minimum amounts of CHO; most diets will include greater amounts of CHO. There is no need to alter the participant's diet unless he or she has been on a CHO-restricted diet.

In preparation for the visit, each participant should:

- Fast for at least 10 hours (but not more than 16 hours) before the test. Fasting should start the night before the test, and should continue up until the start of the test. Participants should not eat or drink anything except water. This means no coffee, tea, soda, cigarettes, alcohol, or chewing gum during the fasting period.
- Refrain from vigorous exercise during the fasting period.
- Refrain from working the night before the morning of the test.
- Discontinue taking any prescription medications that must be taken daily.

Glucose and Insulin Before the Test

- Short-acting insulin analogues (such as lispro or l-aspart) may be administered up to 2 hours before the test.
- Regular insulin may be administered up to 6 hours before the test.
- Intermediate-acting insulin (such as NPH) may be administered on the evening before the MMTT, but not on the morning of the test. Participants managed with intermediate-acting insulin (NPH or Lente) should administer their usual dose on the evening before the MMTT, but not on the morning of the test.
- Long-acting basal (such as glargine) insulin or continuous subcutaneous insulin infusion may be administered before, during and after the test as usual. Participants on glargine may take their usual injection at the appropriate time, and those on continuous subcutaneous insulin infusion may continue with their usual basal settings.

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Target Glucose Level at the Start of Test

The target glucose level at the start of the test is between 70 and 200 mg/dL. Regular insulin or short acting insulin analogues may be used up to 6 and 2 hours before the test, respectively, to achieve the desired glucose level. The investigator and the study participant should discuss the individual situation for insulin administration to attain the goal of meter capillary glucose values within the range of 70–200 mg/dL at the start of the test. For example, as a practical matter, participants may be instructed to check their blood glucose by meter at home 2 hours before the start of the test so that marked hyperglycemia can be treated with a short-acting insulin analogue. Alternatively, participants who arrive at the research unit with elevated blood glucose can receive additional short-acting insulin analogues at the time of their arrival, if the test itself does not start until at least 2 hours after insulin administration and occurs before 10 a.m.

IV Placement During the Test

- The IV should be in place for the duration of the test and must be flushed after each draw with saline solution or heparin flush.
- The participant should remain sitting or resting in bed quietly throughout the test and until the test is completed. However, he or she may engage in quiet, nonstrenuous activities, such as reading, playing cards, or watching TV. The participant may walk to the bathroom between blood draws if necessary.

Testing Instructions

Time Point −10 minutes

- The first sample should be taken at least 10 minutes after establishing the line(s) and when the participant is calm and relaxed (if possible, depending on age) - this is the "−10 minute" sample.
- Draw one 1.2 mL sample into the lavender top K2 ETDA tube for C-peptide. After each sample is collected, the sample tube must be inverted gently at least 8 to 10 times. Chill sample in a bucket of crushed ice or in a refrigerator set at 4˚C for 20 to 30 minutes. At the laboratory, spin the tube in a refrigerated centrifuge (1000–1300 g, ~3000RPM) for 10 minutes. Tubes must be spun within 60 minutes of blood draw. Freeze the sample at -80°C.
- Draw one 1.2 mL sample into the gray top K Oxalate / Na Fluoride tube for glucose. Invert tube gently 8 to 10 times. If it is not possible to centrifuge the sample immediately post collection, chill sample in a bucket of crushed ice or in a refrigerator set at 4˚C for 20 to 30 minutes. Refrigerate the sample no longer than one hour prior to centrifugation.
- Draw sample into the provided K2EDTA tube for glucagon/proinsulin. Invert tube gently 8 to 10 times. If it is not possible to centrifuge the sample immediately post collection, chill sample in a bucket of crushed ice or in a refrigerator set at 4˚C for 20 to 30 minutes. Refrigerate the sample no longer than one hour prior to centrifugation.

Time Point 0 minutes

- The second sample should be taken just before the participant drinks the Boost® High Protein; this is the "0-minute" sample.
- Then the MMTT dose should be given with 6 kcal/kg @ 1 kcal/mL of mixed meal, to a maximum of 360 mL. The participant should consume the MMTT dose in no more than 5 minutes.

Time Points 15, 30, 60, 90, 120, 150, 180, 210, and 240 minutes

- Draw one 1.2 mL sample into the lavender-top K2 EDTA tube for C-peptide levels. Refrigerate the sample
- Draw one 1.2 mL sample into the gray-top K Oxalate / Na Fluoride tube for glucose at each of the time points specified.
- Draw one 1.2 mL samples into the lavender-top K2EDTA tube for glucagon/proinsulin at each of the time points specified.
- Invert all tubes gently 8 to 10 times after collection. If it is not possible to centrifuge the sample immediately post collection, chill sample in a bucket of crushed ice or in a refrigerator set at 4˚C for 20 to 30 minutes.

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Refrigerate the sample no longer than one hour prior to centrifugation.

- At the conclusion of the test, please check blood glucose by glucometer, and administer insulin as per participant's standard insulin plan.

Tube-Processing Instructions

- Spin the collection tubes. Then transfer the plasma into individual vials. Please make sure that each vial is properly identified with a label that indicates the time point.
- Freeze the samples for glucose, C-peptide levels, and glucagon/proinsulin.
- Ship the glucose and C-peptide specimens to the laboratory where the assays will be performed.
- Ship the glucagon/proinsulin specimens to the laboratory where the samples will be stored until testing is initiated at the end of the study.

A clogged line, missed sample, or other deviation from the protocol must be noted on the Comments section of the MMTT specimen transmittal form.

A	B	C
Time (minutes)	**Glucose Sample Taken**	**C-peptide/Sample Taken**
–10	X	X
0	X	X
Participant drinks Boost®		
15	X	X
30	X	X
60	X	X
90	X	X
120	X	X
150	X	X
180	X	X
210	X	X
240	X	X

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