

# Characterization of Insulin and Incretin Secretion in Postpubertal Adolescents and Adults with Cystic Fibrosis~A Pilot Study

**Sponsor:** Cooperative study between CHOP and Upenn, The study is being conducted with general research funds from The Cystic Fibrosis Center and is also supported by the Clinical Translational Research Center (CTRC).

## Brief Description:

- The purpose of this research study is to examine and understand the various mechanisms that contribute to Cystic Fibrosis Related Diabetes (CFRD) and gain a better understanding of potential means to treat it.
- **Type 1 and Type 2 diabetes**-result when either the body does not make enough insulin or the body does not respond correctly to this insulin.
- **Insulin**-a hormone which is made by cells in the pancreas and helps carry glucose (sugar) from the food we eat to the cells of the body for energy.
- In recent years, diabetes has emerged as one of the most significant co-diseases that many cystic fibrosis (CF) patients develop. While CFRD has many features similar to both Type 1 and Type 2 diabetes, it is very different; therefore, treatment and care of CFRD should not be the same.
- Participation in this study will include 2-3 study visits (between 4-6 hours), depending on the individual subject, to the Clinical Translational Research Center (CTRC) at the Hospital of The University of Pennsylvania (UPenn).
- Study visits will be completed over approximately 1 month
- Potential to be compensated up to \$550 (on a Visa gift card) for study participation

## Eligibility:

Currently recruiting patients:

- With cystic fibrosis
- Who are ≥16 years of age

Key Exclusion Criteria:

- If you are a woman who is pregnant or plans to become pregnant within the next year
- Have had acute pancreatitis within the past year
- Have had a prior lung or liver transplant
- Have been diagnosed with severe CF liver disease (defined by portal hypertension)
- Have been diagnosed with fundoplication-related dumping syndrome

## Contact Information:

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## Study Procedures

Oral Glucose Tolerance Test\* (Visit 1):

- We will test your body's response to glucose by taking some of your blood from a blood drawing intravenous (IV) catheter.
- You will then be given a large dose of sugar to drink.
- We will then take blood samples at 60 and 120 minutes after drinking the sugar drink.
- A total of 6 mL (or less than one tablespoon) of blood will be drawn for this test.
- This test is recommended annually for most patients with Cystic Fibrosis in order to screen for CFRD
- If you qualify to participate, you can continue with the study procedures.

\*If an oral glucose tolerance test was completed within 6 months prior to study procedures, this visit is not required

#### Mixed Meal Tolerance Test (Visit 2):

- This test will look at your body's response to food.
- Prior to this visit, you will work with the study team to decide on a breakfast that is appealing to you but is comprised of a specific combination of calories, protein and carbohydrates.
- After you eat, you will have blood drawn from your IV multiple times over a 4 hour period.
- The total amount of blood for this test is about 4½ tablespoons.
- Compensation for this part of the study is \$150.

#### Glucose Potentiated Arginine (GPA) test (Visit 3):

- **Arginine**- a naturally occurring amino acid in your body. In this study it is given in your IV to make the cells in your pancreas secrete the hormone insulin.
- The GPA test will measure the insulin and other glucose controlling hormones which will assist in measuring pancreas cell function.
- After baseline blood levels are drawn, the study team will follow a schedule of administering arginine, glucose, and checking your blood levels over approximately an hour.
- You will be allowed to eat lunch and your blood sugar will continue to be monitored over at least the next hour.
- You may be discharged once we confirm that your blood sugar level has normalized.
- The study team will monitor you closely during this testing, checking your blood glucose levels approximately every 5 minutes.
- The total amount of blood drawn for this test is approximately 9 tablespoons.
- Compensation for this part of the study is \$150

#### Continuous Glucose Monitoring System (CGMS)(optional)(Visit 3):

- CGMS is a way to measure blood sugar continuously for 3 days.
- You will be taught how to use CGMS during a GPA visit.
- CGMS requires the placement of a thin tube under the surface of the skin.
- After you complete 72 hours of CGMS at home, you will send the equipment back to CHOP with an envelope that we will provide.
- Compensation for this part of the study is \$100.

### What are the possible risks associated with the study?

- **Blood sample collections and IV catheter:** The process for collecting blood samples requires a needle to be inserted into a vein. Possible side effects from blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the site of puncture. There is also a slight possibility of infection.
- **Hypoglycemia/Fasting:** Most people do not have medical problems associated with fasting; however, some people have medical conditions that limit their ability to tolerate a fast. If your doctor has told you not to fast, we ask that you not participate in this study.
- **GPA test:** There is the possibility of experiencing a burning or stinging sensation as a result of the glucose infusion. Administration of arginine may briefly cause a metallic taste in your mouth. Rarely, arginine may also cause nausea, vomiting, headache, flushing, numbness, allergy or rash, and irritation of the vein.
- **Pulmonary Function Tests (PFTs):** This test requires blowing rapidly into a device hard several times, which can result in coughing, shortness of breath, dizziness, and the feeling of being light-headed after the test.