Pancreatic enzyme replacement and glucose regulation in Type 1 diabetes

NCT05266963

Informed Consent Document

3/14/2024

Study Title: Pancreatic enzyme replacement and glucose regulation in Type 1 diabetes
Version Date: 31JAN2022
PI: Daniel J. Moore, MD, PhD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This study explores how reduced pancreas size may affect blood sugars in type 1 diabetes. Persons with type 1 diabetes have a smaller than normal pancreas size. In addition to making insulin, the pancreas also makes other enzymes and hormones. This study explores whether replacement of these pancreatic enzymes may help persons with type 1 diabetes achieve better blood sugar control, change any symptoms they may have, and improve how their body responds to meals.

This study will ask you to take pancreatic enzyme supplementation (CREON) and a placebo for a week each in a random order; you will receive both treatments, but you will not know which one you have while you are taking it. You will be instructed to take 2 capsules with all meals and 1 capsule with snacks during both of the weeks. Creon is not approved by the Food and Drug Administration (FDA) for use in type 1 diabetes.

You will also be asked to come in for a mixed meal tolerance test (MMTT) three times to assess your body's response to food; you will have this test in the morning and will be asked to fast overnight the night before. You will be asked to continue wearing your continuous glucose monitor and to share the data with us; you will be asked to record what you eat.

You are being asked to take part in this research study because you have type 1 diabetes and have previously been found to have reduced pancreas volume.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

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Side effects and risks that you can expect if you take part in this study:
There are possible risks of taking Creon. The risks and precautions include:

- Fibrosing colonopathy, a rare, serious adverse reaction has been described in association with high-dose use of pancreatic enzyme replacement in the treatment of cystic fibrosis patients. Caution should be exercised when doses of CREON exceed 2,500 lipase units/kg of body weight per meal (or greater than 10,000 lipase units/kg of body weight per day).
- Care should be taken to ensure that CREON is not chewed or retained in the mouth to avoid irritation of oral mucosa.
- Caution should be exercised when prescribing CREON to patients with gout, renal impairment, or hyperuricemia.
- There is theoretical risk of viral transmission with all pancreatic enzyme products including CREON.
- Caution should be exercised when administering CREON to a patient with a known allergy to proteins of porcine origin.
- Treatment-emergent adverse events occurring in at least 2 patients (greater than or equal to 6%) receiving CREON or placebo are abdominal pain, abdominal pain upper, abnormal feces, cough, dizziness, flatulence, headache, and weight decreased.
- There is no post-marketing experience.
- There are no known drug interactions.

Additionally, there are some things that could cause temporary discomfort. Here are the things you should know about:

- Blood draw: drawing blood can possibly cause bruising, bleeding, discomfort, and infection. Sometimes people may feel sick to their stomach, be lightheaded, or even faint during this procedure. We will attempt to minimize these possibilities by cleaning the skin and having you lie down or sit during this procedure.

There are several other potential risks to changing the way you eat that you should know about:

- Low blood sugar. All persons with diabetes experience low blood sugar some of the time. It is possible that the frequency of low blood sugar could increase during this study. We will ask you to consistently wear your continuous glucose monitor to detect these low blood sugars. If you have a low blood sugar, we will ask you to follow standard treatment recommendations including eating 15grams of glucose and reassessing in 15 minutes if you are able. If you are unresponsive or unable to eat, you should receive glucagon.

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It is possible that you will not directly benefit from this study.

Risks that are not known:
Because this treatment is investigational, meaning non-FDA approved for use in type 1 diabetes, there may be risks that we do not know about at this time.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study: This study may show that persons with type 1 diabetes who have a small pancreas need additional treatments to improve their blood sugar control. This study may improve our understandi ng of blood sugar regulation in type 1 diabetes.

Procedures to be followed:
During this study you will be asked to do the following:

1) Complete a screening visit and sign a copy of this informed consent document.
2) Have a baseline visit where we will obtain your physical measurements and perform an initial MMTT. You will be provided with instructions for the MMTT.
3) Record your daily food intake for the month of the study.
4) Wear your continuous glucose monitor (CGM) during the study.
5) Upload your CGM and pump data, if applicable, and share the data with us.
6) Take CREON capsules or placebo during each of two weeks as instructed.
7) Complete a brief survey and obtain a MMTT at the end of the treatment and placebo weeks.
8) Report any adverse events to us.

Payments for your time spent taking part in this study or expenses:
You will receive $200 for each of the 3 study visits requiring a MMTT to be performed.

We will ask you for your Social Security number and address before you are compensated for taking part in this study.

You may receive up to $600 for taking part in this study. This amount may be taxable and will be reported to the Internal Revenue Service (IRS).

You are not allowed to accept any money for taking part in this study if you are not eligible to receive money from a U.S. person or company or the U.S. government because of U.S. national security and/or foreign policy laws. You can still take part in the study, however, you will not be paid if you are a resident of a country restricted by the U.S. government's comprehensive territorial sanctions or if you are listed on the U.S. Treasury Department's Office of Foreign Assets Control's Specially Designated Nationals (SDN) list of prohibited individuals. You do not have to say why you choose not to be paid.

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Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research. However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

Payment in case you are injured because of this research study:
If it is determined by Vanderbilt and the Investigator that an injury occurred, then you and/or your insurance may be billed for the cost of medical care provided at Vanderbilt to treat the injury. You will be responsible for any copayments or deductibles associated with treatment of that injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt [or the Sponsor] to give you money for the injury.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Daniel Moore at 615-948-6721 If you cannot reach the research staff, please page the study doctor at 615-831-4060.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
- You become pregnant.
- There is concern that continuing the study may be harmful to you.
- You no longer meet the requirements for this study.

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

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Clinical Trials Registry:
A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Confidentiality:
Only research associates in our laboratory or individuals directly involved in the study will have access to data or protected health information. Research records and data with personal identifiers will be stored in our locked offices or on a secure data collection program (REDCap). Only the study doctor and key personnel on the research team will be able to access study patients' names or other identifying data. Data from the study will be maintained in HIPAA-compliant, password-protected databases.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Moore, and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

This study may have some support from the National Institutes of Health (NIH). If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit because of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Results:
A summary of the study results will be made available via https://clinicaltrials.gov/ once the project is complete.

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Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Centerand others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive, or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them knowby using the contact information providedin this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

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If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Study Staff Signature _____

Printed Name and Title _____