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AS MODIFIED
Mar 06, 2024

Consent of an Adult to Be in a Research Study

TITLE: An Exploratory 16-Week Pilot Study Of The Effect And Safety Of A Novel CGM-Based Titration Algorithm For Basal Insulin, With Or Without Non-Insulin Antidiabetic Drugs, In T2DM Participants Treated With Basal Insulin

PROTOCOL NO.: UVA HSR230357
WCG IRB Protocol #20235136

SPONSOR: University of Virginia

INVESTIGATOR: Ralf Nass, MD
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Box 400888
Charlottesville, Virginia 22903
United States

STUDY-RELATED PHONE NUMBER(S): 434-327-0725/434-924-0000, pager 4880 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____ **Medical Record #** _____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

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Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the Novo Nordisk (Bagsværd, Denmark). Grant funding will be used to purchase continuous glucose monitoring (CGM) supplies and blood glucometer and strips. Novo Nordisk will provide Insulin degludec (Tresiba) and insulin pen needles.

Key Information About This Research Study

Principal Investigator:	Ralf Nass, MD 560 Ray C. Hunt Drive, Room 3126 Box 400888 Charlottesville, Virginia 22903 United States 434-327-0725 (24 hours)/434-924-0000, pager 4880
Funding Source:	Novo Nordisk A/S 2880 Bagsvaerd, Denmark

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What is the purpose of this study?

The purpose of this study is to compare the effect of using an experimental CGM-based algorithm (complex mathematical formula) to adjust your insulin dose as compared to using self-monitoring blood glucose (SMBG are also called fingersticks) titration algorithm to adjust your insulin dose. The CGM-based algorithm is investigational and is not approved by the U.S. Food and Drug Administration (FDA). The CGM-based algorithm uses blood glucose values collected from the CGM that you will wear during the study. The SMBG algorithm is routinely used when you work with your doctor to adjust your insulin parameters. The SMBG algorithm uses blood glucose values that you collect during the study. The SMBG algorithm is different from the CGM based algorithm.

The CGM-based algorithm has been tested in computer simulation only. It has not yet been proven to be safe or helpful. However, the FDA has allowed the algorithm to be used in this research study for people with Type 2 Diabetes.

All study participants will receive Insulin Degludec (Tresiba) to use as your basal insulin. This basal insulin is an FDA approved medication for treatment of Type 2 Diabetes and will be used as described on the FDA approved label. Insulin pen needles will be provided as well, but you can choose not to use this supply.

You are being asked to take part in this study because you have received the diagnosis of Type 2 Diabetes and are currently using basal insulin each day for the past 90 days as part of your regular clinical care.

Why would you want to take part in this study?

You may or may not be helped by being in this study, but the information gained by doing this study may help others in the future.

Why would you NOT want to take part in this study?

You might not want to take part in this study because:

- this study is using an algorithm that is not approved by the FDA; it is considered investigational.
- your participation in the study will last for about 18 weeks.
- you will need to collect a fasting SMBGs before breakfast each day of the study.

What will I have to do if I take part in this study?

Full details of all the procedures are found later in this form. If you agree to take part in this study, you will:

- attend a screening visit. You can attend this appointment in person or a video visit. If this is done with a video visit, you may use a physical exam record from the previous 12 months, and you may go to a local lab to have your blood drawn.
- be trained in the use of the study equipment.
- be trained on hypoglycemia symptoms, hyperglycemia symptoms and how to treat these symptoms.
- receive study issued CGM supplies, blood glucometer & strips to use during the study.
- use the FDA approved Insulin Degludec (Tresiba) pen during the study.
- need to have glucagon at home to use in the event of a severe low blood glucose level.
- be trained on how to collect a large droplet of blood for a hemoglobin A1c samples at home three times during the study. You will then ship this blood sample to a laboratory in a pre-paid package.

What is the difference between being in this study and getting usual care?

If you take part in this study, the following things will be done differently than if you do not take part in this study:

- (EXP Group): You will use continuous glucose monitor (CGM) based titration algorithm
- (CTR Group): You will use standard titration by self-monitoring blood glucose (SMBG)
- ALL participants in both EXP and CTR Group
- (ALL): You will wear a blinded (you will not have access to any CGM measurements or alarms) CGM for 14 days at the start of the study.
- (ALL): You will use Insulin Degludec (Tresiba) during the study.
- (ALL): You will need to collect a fasting SMBG each day of the study.
- (ALL): You will need to attend check-in visits with the study team every 4 weeks.
- (EXP Group): You will wear an unblinded (you will have access to CGM measurements or alarms) CGM for 16 weeks.
- (CTR Group): You will wear a blinded CGM for 16 weeks.
- (EXP Group): You will receive weekly insulin dose recommendations made by the CGM-based algorithm and approved by the study physician.
- (CTR Group): You will receive weekly insulin dose recommendations based on the pre-breakfast SMBGs on Day 5, 6, and 7 and approved by the study physician.
- (CTR Group): You will be asked to confirm receipt of the insulin dose recommendations within 24 hours of receiving this information.

What other treatments may I receive if I decide to not take part in this study?

The following alternative treatments are available to you if you decide not take part in this study:

- You may continue your diabetes care using personal insulin pen as you normally do.

How many people will take part in this study?

Up to 60 people will be in this study screened with the intent to complete 30 participants.

How long will this study take?

Your participation in this study will require 10 study visits over approximately 18 weeks. The consent visit (visit 1) and the screening appointment (visit 2) will take about 1-2 hours each. CGM training (visit 3) will take about 1 hour. The blinded CGM data collection (visit 4) will take 14 days at home. The Randomization Visit (visit 5) may take about 1-2 hours as you will receive additional training on the study equipment. You will have three check-in visits (visits 6-8) will last about 15-30 minutes. The Study End Visit (visit 9) may take about 1 hour. There will be a post-study check-in visit (visit 10) that will take less than 15 minutes. The study team would prefer that these visits are completed in-person at the clinic, by phone or telecommunications (e.g., Zoom

meeting). The study team may choose to ask that you extend your participation or discontinue your participation in the study if there is a concern about your data collection or other safety concerns.

What will happen if you are in the study?

Visit 1: Sign Consent Form (visit will last about 1-2 hours)

The consent form will be discussed with you in great detail to make sure that you understand the study and your responsibilities as a study participant. If you agree to participate, you will sign this consent form before any study related procedures take place.

Visit 2: Screening (visit will last about 1-2 hours)

Before you can start in the study, there will be a screening period. You will have tests and procedures during this time to make sure you are eligible, and it is safe for you to participate. These include the following:

- A review of your medical and surgical history, allergies, and current medications.
- A physical examination and vital signs (height, weight, blood pressure, heart rate, temperature). A physical history dated within the last 18 months may be substituted.
- Demographics (date of birth, gender, race, and ethnicity)
- Contact information (name, phone number, e-mail address, mailing address)
- Medical history including diabetes history of hypoglycemia and hyperglycemia events
- List of current medications
- HbA1c (your blood glucose average over 8-12 weeks)
- Standard blood tests to check your cholesterol, liver, kidneys, and thyroid functions. (Blood test obtained within 14 days prior to enrollment may be used for eligibility purposes.)
- Urine or blood pregnancy test for all females of child-bearing potential. This test must be negative in order to be enrolled in the study.

If these tests show you are eligible, you will be enrolled in the study. During this study will be asked to complete a 10-minute survey that ask about:

a. Gender
b. Race
c. Ethnicity
d. Marital status
e. Level of education
f. Employment status
g. Household income
h. Health insurance status

Visit 3: Continuous Glucose Monitor (CGM) Training (visit will last about 1 hour)

The study team will teach you how to properly use a Dexcom CGM. You may be instructed to watch the Dexcom training video (https://www.dexcom.com/training-videos). You will be provided with the appropriate CGM supplies to use during the study.

Visit 4: CGM Run-In Phase (14 days)

You will be asked to wear the study CGM at home for 14 days. The CGM values will be blinded to you, meaning you will not see your glucose values. You will be asked to follow your usual basal insulin doses. You will be asked not to change your insulin parameters or add medications that could lower your glucose during this time. The study physician may ask you to extend or repeat this run-in phase if additional CGM data is needed.

Visit 5: Randomization and Training (visit will last about 1-2 hours)

You will be asked to collect a Hemoglobin A1c sample (a large blood drop) and ship it to the laboratory in the pre-paid package.

You will be randomly assigned (like the flip of a coin) to 1 of 2 study treatment groups. For every one person randomized to the Control (CTR) Group, two people will be randomized to the Experimental (EXP) Group. Neither you nor your doctor can choose which treatment you are assigned.

EXPERIMENTAL GROUP: Continuous Glucose Monitoring (CGM) Based Titration

CONTROL GROUP: Standard Self-Monitoring Blood Glucose (SMBG) Titration

Experimental Group

If you are assigned to the CGM-based titration group, you will get an insulin dosing recommendation on the study app during each week of the study. These dosing recommendations are generated from using your CGM values in the study algorithm. The study physician will review and approve these dosing recommendations prior to receiving the information. The study physician will only modify the dosing recommendation for safety reasons. You will be asked to talk to the study physician if you want to change the dose that has been recommended to you.

What you will need to do during the study:

- You will need to use the study glucometer to measure your PRE-BREAKFAST (FASTING) SMBG each day of the study.
- The PRE-BREAKFAST (FASTING) SMBGs on Day 5, 6, and 7 after you change your insulin parameters are very important measurements. You will need to enter this information into the study app.
- You will need to use the insulin dose you receive from the study app for that week.
- You will need to document any hypoglycemia events in the study app.
- At the end of each week, you will be asked to record the insulin dose that you actually took each day of that week.

Control Group:

If you are assigned to the standard SMBG titration group, you will receive a weekly recommended insulin doses from the study app (on personal cell phone or cell phone provided by study team) based on a mean (average) of 3 pre-breakfast SMBGs measured on Day 5, 6 and 7 after the last dose change. The dose recommendation will be based on the titration algorithm. Dosing recommendations will be performed one time weekly unless the study physician has safety concerns. You will be asked to talk to the study physician if you want to change the dose that has been recommended to you.

What you will need to do during the study:

- You will need to use the study glucometer to measure your PRE-BREAKFAST (FASTING) SMBG each day of the study.
- The PRE-BREAKFAST (FASTING) SMBGs on Day 5, 6, and 7 after you change your insulin parameters are very important measurements. You will need to enter this information into the study app.
- You will be asked to confirm receipt of this dose within 24 hours of receiving this information.
- You will need to use the insulin dose you receive from the study app for that week.
- You will need to document any hypoglycemia events in the study app.
- At the end of each week, you will be asked to record the insulin dose that you actually took each day of that week.

Training (all participants)

Personal phone / Study phone

A study smartphone may be provided for if you prefer not to use your personal smartphone during the study. If you elect to use a phone provided by the study team, you will be trained in the basic functioning of the phone (e.g., charging, password entry, accessing apps).

If you choose the study phone option, you will be provided with a study phone with a data plan, the Dexcom G6 app (EXP Group only) and access to the study application for the duration of the study. If you choose to use your personal smartphone, the Dexcom G6 app and the study app will be downloaded to your phone. For iOS (Apple) phone users, the study team will need to add the unique device identifier (UDID) of your phone into our account. All participants will be asked to verify the successful installation of apps and account access.

CGM & Glucometer

You will be trained in the use of the study CGM, and glucometer based on your prior experience with this equipment. EXP Group participants will receive unblinded CGM supplies while CTR Group participants will receive blinded CGM supplies. You will receive a study glucometer and test strips to collect SMBGs.

Study App

Prior to initial use, the study app will be downloaded by a study team member onto your compatible phone (or phone provided by study team). The study app will permit you access to the website.

Qualified study team members will train you in performing specific tasks including the following:

- How to start a new CGM session.
- How to connect the CGM transmitter as well as troubleshooting techniques for reconnecting.
- For CGM-based titration arm participants (EXP Group): How to view the CGM information including the most recent CGM value, trend arrow, and CGM graph. Low and high threshold alerts will be set. You may choose the threshold alert values, but the low alert may not be set to <70 mg/dL and the high alert may not exceed 300 mg/dL.
- How to enter pre-breakfast SMBGs.
- How to receive new insulin dose recommendations and how to access past recommendations.
- How to record an injected dose in DiAs
- How to record hypoglycemic events.

Hemoglobin A1c home kits
You will be provided with three kits to collect a hemoglobin A1c sample at home. The study team will review the instructions with you to ensure that you are collecting the sample properly. These samples will require a small amount of blood to be placed in a tube. You will then ship this blood sample to a laboratory in a pre-paid package.

Insulin Degludec (Tresiba) pen
You will be trained in the use of the Insulin Degludec (Tresiba) pen by a study team member after randomization. We expect that no retraining will be necessary, but a package insert (instructions and information) will be provided.

Glycemic Treatment Guidelines
The study team will teach you how to recognize the symptoms of hypoglycemia and hyperglycemia. You will be instructed to obtain a confirmation SMBG when you experience these symptoms. Additionally, if you are assigned to the EXP Group, the CGM will alarm when the blood glucose reads below 70 mg/dL or above 300 mg/dL. You will be instructed to take a SMBG if the CGM alarms. You will be asked to record the SMBGs in the study app.

You will be provided a handout on what to do when you experience these symptoms or the CGM alarms.

Glucagon Emergency Kit
A home glucagon emergency kit will be required. A glucagon prescription from the study physician can be provided as needed.

Visit 6-8: Check-In Visits (visit will be about 15-30 minutes)

About every 4 weeks
These visits may occur in the clinic, phone/telecommunication (something like a Zoom Application).

You will check in with the study team every month until the end of the study. During these check-in calls, the study team will:

- review any questions that you have about the device and the study apps
- review any medical illnesses or medications that you may have started
- review of your CGM
- review of your SMBG values
- review of any low blood glucose values

- review of any high blood glucose values
- review any technical questions that you may have about the study equipment

You may contact the study team at any time between these visits if you have any questions.

The study team will also check to make sure that the data was completely downloaded or uploaded. If the study team has difficulty viewing your data, the team may ask you to download the data on any relevant devices, if applicable.

Visit 7 only
You will be asked to collect a Hemoglobin A1c sample and ship it to the laboratory in the pre-paid package. The study team can also schedule a clinic appointment if you would like their assistance with collecting this sample.

Visit 9: Study End Visit (visit will about 1 hour)

This visit may occur in the clinic or by telecommunication (something like a Zoom Application).

At the final visit, you will be asked to complete the following:

- You will be asked to collect the final Hemoglobin A1c sample and send it to the laboratory in pre-paid packaging.
- The study team will ask you questions about the study, the study device, any new medications, any updates to medical conditions, and any health-related problems.
- You will be instructed on how to transition back to your home insulin regimen. There may be a risk of severe hypoglycemia and severe hyperglycemia as you return to your usual insulin parameters. The study clinicians will be available if you have questions. Study clinicians will decide if your insulin dose should to be changed, and what those changes will be. The study clinicians will continue to be available during the post study check-in to make sure your transition is smooth.
- You will be asked to return all study equipment (e.g., study CGM, insulin, study glucometer, study phone if provided, etc.) either via mail or at an office visit. The study team will give the glucometer back to you after they have obtained the data from the equipment or the glucometer app. You will not have to pay for any costs of shipping devices.

If you need to stop participating in the study before its completed (for example you were unable to complete any visits after visit 5), you will be asked to complete final visit 9.

Visit 10: Post-Study Check-in Visit (visit will last less than 15 minutes)

Approximately 48 hours after completing the study, the staff will contact you via phone/email/text to see if you have had any health issues since completing the study and to verify that you have returned the study devices.

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Study Schedule

	Consent	Screening	Training	CGM Run-In Phase	Randomization		Check-In Visit		Check-In Visit		Check-In Visit		Study End Visit	Post-Study Check-In
Location VC=Videoconferencing	Clinic or VC	Clinic or VC	Clinic or VC	Home x 2 weeks			Clinic/ Phone/ VC		Clinic/ Phone/ VC		Clinic/ Phone/ VC		Clinic/ Phone/ VC	Clinic/ Phone/ VC
Visit	1	2	3	4	5		6		7		8		9	10
Intervention Phase (week)					0	1-3	4	5-7	8	9-11	12	13-15	16	Post Day 2-7
Informed Consent	X													
Eligibility Assessment		X												
Medical History		X												
HbA1c – Central Lab					X				X				X	
HbA1c – Local Lab		X												
Laboratory testing (CMP & TSH) if needed		X												
Pregnancy Test (if applicable)		X												
Physical Exam		X												
Vital Signs (height/weight)		X												
Demographic Survey		X												
CGM Training			X		X									
Randomization					X									
DiAs Training					X									
Insulin Degludec Pen Training/Review					X		X		X		X			
Review of CGM data (EXP only) & SMBG data for hypo-and hyperglycemic events & AEs (both groups)						X	X	X	X	X	X	X	X	
Insulin dosing changes once per week at Day 7 in both groups						X	X	X	X	X	X	X	X	

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You need to attend each study visit as instructed by the study team.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- You will need to answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over the counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.
- You should not share the study provided insulin.

Blood Testing:

The total amount of blood we will take for your screening hemoglobin A1c test will be less than a ½ teaspoon of blood. This blood test is used to monitor how well you are managing your diabetes. The hemoglobin A1c samples collected at home with require a large drop of blood for each of the three samples.

If additional labs are needed (for example: liver function tests, hematocrit, pregnancy, and thyroid stimulating hormone), we will take less than 7 teaspoons of blood.

When these tests are done any left-over sample will be thrown away or they will be de-identified. This means there is no information that could be used by anyone to determine who the sample came from.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

If you want to know about the results before the study is done:

During the study, you are using an investigational application. The purpose of the application is NOT to diagnose any disease or abnormality you may have. Because the application is investigational, there is no way for the study leader to understand if the results are “normal” or

"abnormal". However, if any results are concerning, your study leader will let you know. In addition, as the research moves forward, your study leader will keep you informed of any new findings about the research itself that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you may ask for more information about the study results.

What are the risks of being in this study?

Risks related to the use of insulin degludec (Tresiba):

Likely

- Allergic reaction
- Risks related to using the algorithm (standard and CGM based)
- Hypoglycemia
- Hyperglycemia
- Increased glucose variability

Risks of SMBGs (fingersticks):

Likely

- Pain at site of lancet (finger-pricking needle) use
- Bleeding at site of lancet use

Less Likely

- Incorrect information from a false low or false high fingerstick value

Rare but serious

- Infection at site of lancet use

Risks related to using a Continuous Glucose Monitoring Sensor:

Likely

- Failure or lack of sensitivity of the continuous glucose monitor sensor that requires replacement and or insertion of new sensor in your abdomen
- Discomfort from insertion of sensor into the skin
- Acetaminophen (Tylenol) taken in high doses (e.g., more than 1000 mg every 6 hours in adults) may falsely raise sensor glucose readings

Less Likely

- Bruising less than ½ inch
- Bleeding less than ¼ teaspoon

- Sensitivity to adhesives with use of continuous glucose monitor resulting in skin irritation, redness, blistering, scarring, systemic allergic reaction (shock with breathing problems, heart failure)
- CGM sensor reads higher or lower than your actual glucose level
- CGM sensor stops working or cannot communicate with the system.

Rare but serious

- Swelling or redness at insertion site
- Psychological reaction to viewing the continuous glucose monitor information or attending to continuous glucose monitor alarms or finger stick blood glucose values.
- Breakage of the continuous glucose monitor sensor under the skin with possible symptoms of skin irritation and inflammation. If a sensor breaks and no portion of it is visible above the skin, do not attempt to remove it. Please call the study team or seek immediate medical assistance. Seek professional medical help if you have symptoms of infection or inflammation – redness, swelling or pain – at the insertion site.
- Bloodborne pathogen, such as Hepatitis B, if the shared CGM transmitter is not cleaned thoroughly with a diluted mixture of bleach or another appropriate cleaner after use per hospital approved cleaning procedure.

Risks and side effects related to treating type 2 diabetes (with or without being in a study):
Likely

- Risk of possible mild to moderate low blood sugar and possible symptoms of low blood sugar, such as sweating, trembling, difficulty thinking, dizziness, and feeling uncoordinated.
- Risk of possible mild to moderate high blood sugars and possible symptoms of high blood sugars such as thirst and frequent urination. You may have a higher level of sugar in your urine.

Rare but serious

- Risk of severe temporary low blood sugar (hypoglycemia) that can lead to unconsciousness, hypoglycemic seizure, hospitalization or even death.

Risks of Sharing Insulin Degludec (Tresiba)

Do not share the Insulin Degludec (Tresiba) with anyone. It is prescribed only for you and could hurt someone else. Keep it out of reach of children and people that are not able to read or understand the label.

Risks of Device Reuse
The study CGM system is labelled for single use only. The sensor (the component of the system that enters the skin) will be single use only. The receiver (a handheld device not attached to any system element puncturing the skin) may be reused during the study after cleaning the device using a hospital-approved cleaning procedure. The transmitter which sits on the sensor may be reused after cleaning the device using a hospital-approved cleaning procedure.

Risks of having your blood drawn:
- pain (common),
- a bruise (sometimes),
- fainting or passing out (not very often), and
- infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:
- hepatitis,
- HIV (Human Immunodeficiency Virus), or
- other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV or any other infection that may affect your clinical care, we will tell you the results and help you understand what the results mean for you.

Risks associated with performing a serum (blood) or urine pregnancy tests (women who are able to become pregnant):
Less Likely
- False positive or false negative results.

Risks for women:
- Being in this study might hurt your unborn baby, so you will not be able to join or stay in the study if you become pregnant. If you have questions about birth control, please ask the study leader. If you are pregnant now or get pregnant during the study, please tell us right away.

Blood Donation
If you participate in this study, it may affect your ability to donate blood. If you have any questions call the organization where you donate blood and talk to one of their nurses.

Risks from Completing a Survey

- Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

Other unexpected risks:

You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated for your condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- managing your condition as recommended by your endocrinologist

If you are an employee of UVA, your job will not be affected if you decide not to participate in this study.

If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will be paid $300.00 by check for finishing this study. You will be paid up to $100 if you attend in-person visits, up to $300, totaling a maximum payment of $600. The payment may be reported to the IRS as income.

- Completion of Visit 4 (CGM Run-In Period): $50
- Completion of Visit 6-8 (Check-In Visits): $50 per visit ($150 total)
- Completion of Visit 9 (Study End Visit): $100
- Travel Compensation: $100 if you need to travel for an in-person visit (up to $300 total)

You should get your payment about 6 weeks after finishing the study and after returning the study equipment (e.g., CGM supplies, insulin, etc.) The study glucometer can be returned to you after the data is downloaded from the glucometer or the glucometer's app.

If you decide not to finish the study, you will be paid for the visits that you have completed.

If the study leader says you cannot continue, you will be paid for the visits that you have completed.

Will being in this study cost you any money?

You and/or your insurance company must pay for the glucagon emergency kit, which is a medication to help with severe low blood sugar. A prescription for this medication is considered part of usual care for a person with Type 2 Diabetes. You will be responsible for any costs related to using your personal smartphone during the study.

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: lab tests, physical examination, vitals, pregnancy tests, study CGM supplies, study insulin, study glucometer supplies, and study phone with study apps.

Your travel and parking costs will also be reimbursed if you have an in-person visit(s). See the "Will you be paid for being in this study?" section of this form for more information.

What if I do not want to be in this study?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study. Some of the reasons for doing so may include:

a) your study leader is concerned about your health
b) your condition gets worse
c) the side effects of the treatment are too dangerous for you
d) new information shows the treatment will not work or is not safe for you
e) you do not follow your doctor's instructions
f) the study closes for safety, administrative or other reasons

If you decide to stop being in the study, we ask that you notify the study leader and/or research team so any scheduled visits may be cancelled. The study CGM and other supplies remain the property of the study team and will need to be returned to them.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

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How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address, and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers at both clinic sites to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA).
- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.
    - Data may be shared, in an unidentified format, with Novo Nordisk A/S, and this data may be used for commercial purposes.

Some of the people outside of UVA who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you such as name, address, or phone number.

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

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the study leader listed on this form or complete the "Leaving the Study Early" part of this form and return it to the study leader. Then you will no longer be in the study. The study leader will still use information about you that was collected before you ended your participation.

Please contact the Principal Investigator listed BELOW to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Ralf Nass, MD
560 Ray C. Hunt Drive, Room 3126
Box 400888
Charlottesville, Virginia 22903
United States
Telephone: 434-327-0725/434-924-0000, pager 4880 (24 hours)

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research participant by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22903 Telephone: 434-924-2620

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When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or clientcare@wcgclinical.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

Would you agree to the electronic consenting process?

The study team will provide you with the best way for you to sign this consent form. Signing the consent form can occur in person or electronically. You will need to provide two forms of identification to verify your identity prior to signing the consent form electronically.

You do not have to agree to sign the consent form electronically.
PLEASE INDICATE YOUR CHOICE BELOW:

Yes_____ I agree to sign this consent form electronically.
If you agree to electronic consenting, the study team will ensure that you have a copy of the signed consent.
No_____ I DO NOT agree to sign the consent form electronically.

Would you like the study team to communicate with you by email or text message?

If you choose to communicate with the study team by unsecure email (email that is not encrypted) or text message to your personal phone, there is some risk that your health information could be read or accessed by someone else while the information is sent or saved by your email or phone provider.

Your personal email or phone provider may also share or release your information because they do not have to follow the privacy laws that UVA follows. Sometimes email and phone providers release information to marketing companies for use in direct advertising. If you choose to communicate by email or text messaging, UVA cannot control this potential loss of privacy, but we want to tell you about this possible risk.

You do not have to agree to communicate with the study team by email or text message to be in this study. If you agree to texting or emailing, the study team will collect your phone and /or email address from you that you would like them to use to contact you. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

You do not have to agree to use email or text message to be in this study.
PLEASE INDICATE YOUR CHOICE BELOW:

Yes_____ I agree to be contacted by email or text.
If you agree to texting or emailing, the study team will collect your phone and /or email address that you would like them to use. Please note, if you agree to text messaging, charges may apply depending on your data/text plan with your phone provider.

No_____ I DO NOT agree to be contacted by email or text.

Would you like to be contacted about future studies?

The researchers in this study would like to know if you wish to be contacted regarding participation in additional studies that may be appropriate for you. By agreeing to be contacted, you will allow a qualified member of the study team to contact you in the future to ask if you want to participate in additional studies. You have no obligation to participate in any study.

Declining will have no influence on your present or future status as a patient in this clinic. You will receive the same care as any other patient seen in this clinic. There will be no penalty or loss of benefits to which you are otherwise entitled. Your clinic records will indicate that you do not want to be asked about future research by or through anyone but your treating physician.

Participation in research may involve some loss of privacy. However, your records will be handled as confidentially as possible. Access will be limited to the study team organizing the study. No information will be used for research without additional permission. Your contact information will not be shared with anyone outside of UVA without your permission.

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You do not have to agree to be contacted about future research to be in THIS study.

PLEASE INDICATE YOUR CHOICE BELOW if you are willing to be contacted about any future research studies.

____ Yes, I agree to be contacted about future research studies.
____ No, I do not want to be contacted about future research studies.

_____

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Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form, it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below, you confirm that you have fully explained this study to the potential participant, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Notification of My Health Care Provider

Please indicate below whether you want us to notify your health care provider that you have agreed to take part in this study.

____ Yes, I want the study doctor to notify my health care provider that I have agreed to take part in this study.
Health Care Provider Name: _____
Health Care Provider Address:
Study team will send a copy of the consent form to the health care provider.

_____ No, I do not want the study doctor to notify my health care provider that I have agreed to take part in this study, or I do not have a health care provider.

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Leaving the Study Early

Check one option below:

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.

The follow up information will be collected by the study team:

- Obtaining information from my medical records
- Phone call
- In person follow up visit if requested by the study physician

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow-up information from my medical records.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the participant and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE