Northwell Health

Campus: Northwell Health, North Shore University Hospital, Divisions of Endocrinology and Nephrology, Department of Medicine

Consent for Participation in a Research Study

Title: Assessment of Glycemic Control in Patients with Type 2 Diabetes Mellitus and Late Stage Chronic Kidney Disease

Principal Investigator: Lubaina Presswala DO
Co-Investigators: Yael Harris MD, Steven Fishbane MD

Sponsor: Internal Departmental Initiated Research Study at Northwell Health Divisions of Endocrinology and Nephrology

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

This consent form will explain:

- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?
This research study is being done to evaluate how to best monitor diabetes control in patients with Type 2 Diabetes Mellitus (T2DM) and advanced chronic kidney disease (CKD) stages 3b-5. The study investigators perform certain blood tests regularly in order to help answer this question, such as the Hemoglobin A1c. However, it is not known if this test is accurate when patients with diabetes also have kidney disease. The primary purpose of the study is to understand how accurate tests like hemoglobin A1C are when kidney disease is present. A second purpose is to better understand how often low or high blood sugars occur in patients with diabetes and kidney disease.

Why is this research?
This is a research study because there is very limited evidence in understanding the best marker for diabetes control in T2DM patients with concurrent CKD 3b-5. Thus, the investigators intend to find out which marker is the best amongst HbA1c, fructosamine, and continuous glucose monitoring (CGM) data for diabetes management in patients with CKD 3b-5. This study will also investigate the incidence of hypoglycemic episodes and the variability in hypoglycemia and hyperglycemia in this specific patient population. The investigators hope that the results will improve diabetes management in patients with T2DM and CKD stage 3b-5.

You are being asked to participate in this study because you have Type 2 Diabetes and chronic kidney disease.

How many people will take part in this study?
This research study hopes to enroll 80 patients from all sites. Patients will be included from both Northwell Health Divisions of Nephrology and Endocrinology, and Winthrop University Hospital's Division of Nephrology.

How long will you be in this study?
You will participate in this study for 14 days. At your first visit on Day 0, we will explain the study to you and obtain your voluntary consent for study participation. On Day 0, we may collect bloodwork if not already noted in your medical chart from the previous 12 weeks to screen you for participation. If you meet inclusion criteria to participate in the study then you will return on Day 1 and a research personnel will place a subcutaneous glucose monitoring device under the skin on the back of your arm. You will be asked to wear this device for 14 consecutive days. This device will record your glucose continuously for 14 consecutive days. You will be asked to calibrate the device daily with a fingerstick done on your glucometer. All questions regarding this device will be answered on Day 1 and throughout the 14-day period. You will return to the research site on Day 14 to get the device removed by a research personnel and bloodwork will again be collected on Day 14. Returning the CGM device to the research personnel after wearing it for 14 consecutive days and getting bloodwork on Day 14 will complete your participation in the study.

What will happen in this research study?
On Day 0 of the study you will meet with a member of the research team who will verify the following information: your age; sex; race; the number of years you have had Type 2 Diabetes; the names of your medications; whether you have heart disease, congestive heart failure, cardiovascular disease, or cancer; the reason you have kidney disease; and how many years you have had kidney disease based on information collected from your medical chart. At this time, a research personnel will evaluate your medical chart for blood results of complete blood count (CBC) and basic metabolic profile (BMP) from previous 12 weeks to determine your eligibility to participate in the study. If CBC and BMP was not done in the previous 12 weeks, blood will be drawn on Day 0 and you will be notified if you are eligible to be included in the study based on lab results. If you are eligible to participate then you will be advised to return to clinic on Day 1 and a continuous glucose monitor - the *Freestyle Libre* - will be placed on you. A continuous glucose monitor is commonly used in people with diabetes to see how their diabetes is being controlled throughout the day (without having to check finger stick values frequently).

You will continue the same medications that you have been taking for diabetes. You will return on Day 14 of the study at which time the continuous glucose monitor will be removed. On this day, you will also have bloodwork collected. The amount of blood drawn will be about 2-3 teaspoons.

What are the risks of the research study? What could go wrong?

Continuous Glucose Monitor: There is a small but possible risk of a skin reaction or infection at the subcutaneous site on your arm where the continuous glucose monitor is inserted.

Blood-Drawing: There are no major risks of having blood drawn. It can be uncomfortable and can sometimes cause a bruise. In rare cases, it can cause fainting. Only trained staff will draw your blood.

Breach of Confidentiality: A breach of confidentiality occurs when your private medical information is unintentionally disclosed to someone not authorized to receive it. The study team has measures in place to prevent such an accidental disclosure.

What are the benefits of this research study?

A possible benefit you may experience from this study include better understanding of how well your diabetes is being controlled. It may also help us know how useful continuous glucose monitoring is for evaluating diabetes control in patients with Type 2 Diabetes and chronic kidney disease.

Are there any costs for being in this research study?

You will not have any added costs from being in this study. If bloodwork is collected on Day 0, your insurance will be billed for reimbursement as that will meet criteria for routine clinical care. Bloodwork collected on Day 14 will be funded by the research funds. All study related visits and the continuous glucose monitor will be given to you at no cost. You will be continued on your current diabetic medications.

Will you receive any payments for participating in this research study?

You will not receive any payments for participating in this research study.

What are your rights as a research participant?

Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health.

Could you be taken off the study before it is over?

It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.
- if it is decided that it would be in your best interest to change your diabetes medications

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be immediately notified in case any new information is learned that may negatively impact your health (as determined by the researchers) at any time during your participation. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.
Investigators will share information collected from this research study with:

- data safety monitoring board,
- clinical staff not involved in the study who may be involved in participant's treatment with patient consent,
- health insurers or payers

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies such as *the Food and Drug Administration(FDA), National Institute of Health (NIH), etc.*
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversee research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Lubaina Presswala
865 Northern Blvd, Suite 203
Great Neck, NY 11020
Phone: 516-708-2540

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected.

Does the investigator of this study receive money if you take part?
The investigators on this study do not receive any money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Lubaina Presswala at 516-708-2540. If you have questions about side effects or injury caused by research you should call Dr. Lubaina Presswala at 516-708-2540. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910.

A signed copy of this consent form will be given to you.

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date

(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name