Official Title: A Trial of CGM Technology in Preoperative Assessment Clinic

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Wake Forest®
School of Medicine

Department of Anesthesiology

TRIAL OF CGM TECHNOLOGY IN PREOPERATIVE ASSESSMENT CLINIC

Informed Consent Form to Participate in Research
Susan R. Vishneski, MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to collect data on blood glucose using a continuous glucose monitor before your upcoming surgery. We are evaluating glucose management with surgery subjects to see if there is a better way to manage your glucose perioperatively to improve surgery outcomes. You are invited to be in this study because you have diabetes and may require treatment with insulin during your surgery. Your participation in this research will last about 1-14 days depending on date of your surgery after your preoperative assessment clinic appointment.

Participation in this study will involve you potentially being randomized (like the flip of a coin) to either wear a Libre 2 continuous glucose monitor (CGM) or a Libre Pro CGM. The CGM will be placed on the back of your arm before your surgery at your preoperative assessment clinic appointment. Participants using Libre 2 CGM will be able to see glucose values in realtime through application on their smartphone device. You will be asked to scan your sensor at least every 8 hours at home. These glucose values will also be available to your perioperative team who will review within 1 week of your preoperative clinic assessment appointment. Your perioperative team may provide recommendations for how to improve control of diabetes prior to surgery based on the CGM data. Participants using Libre Pro CGM will not be able to see glucose values in realtime, will not be asked to scan your sensor, and will not receive recommendations based on the CGM data. The device can stay in place up to 14 days at a time. The device is able to be worn with showering or bathing. It will be removed if you undergo imaging with MRI. Research staff will provide contact information to you so that if any questions arise you can call at any time.

All research studies involve some risks. A risk to this study that you should be aware of is that placement of the device requires the use of a small needle. Discomfort from inserting the device is minimal and brief, only lasting about 1-2 seconds when the continuous glucose monitor is placed on the back of the arm. The needle is instantly withdrawn, and a very small piece of plastic tubing will remain just under the skin that continuously reads your sugar while you are wearing it. Regardless of the group you are randomized to, you will have the normal blood glucose checks with a fingerstick while you are in the hospital. There are no additional blood draws involved in this study. You will be treated for elevated glucose levels as you normally would while hospitalized. The device will be removed prior to your hospital discharge.

We hope we can show that future patients with diabetes may benefit from information collected in this study if the study shows that continuous glucose monitors can be helpful to improve your glucose control prior to surgery.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include to not have a continuous glucose monitor placed and to continue with the normal standard of care during your hospital stay.. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is the Principal Investigator, Susan R. Vishneski, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study her contact information is: [redacted].

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Research Subject Advocate at Wake Forest at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have diabetes and are expected to need blood glucose monitoring and possibly treatment with insulin during your surgery and subsequent hospitalization. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see if continuous glucose monitors would work well to improve glucose control leading up to a planned surgery.

Pilot Data Study:
This study is being done with placement of a continuous glucose monitor(s) to monitor blood glucose. The purpose of this is to see if continuous glucose monitoring prior to surgery can improve glucose levels in the perioperative period. This study uses the FreeStyle Libre Pro and the Freestyle Libre 2, which have been authorized by the U.S. Food and Drug Administration (FDA) for use in the outpatient setting.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Two hundred and twenty subjects at Atrium Health-Wake Forest Baptist will be enrolled in this

study. Twenty of these subjects were enrolled as part of the pilot trial of this study. In order to enroll 220 subjects who complete the study, we may need to consent as many as 240 subjects.

WHAT IS INVOLVED IN THE STUDY?

You will be approached during your visit to the preanesthesia assessment clinic to determine your interest in participating in this study on your day of surgery. If you wish to participate, you will be asked to sign this informed consent form. You will then be randomized (like the flip of a coin) to either have the Libre 2 continuous glucose monitor (CGM) or a Libre Pro CGM placed on the back of one of your arms. You will have the device placed during your preanesthesia visit with contact information of research staff. Research staff will then meet you in the holding room on the day of your arrival to ensure the device remains in place. If you have the Libre 2 CGM placed, you will be asked to scan the sensor at least every 8 hours at home. Also, if you have the Libre 2 CGM placed, your perioperative team will be able to review your CGM data prior to surgery, and may contact you with additional recommendations for how to improve control of your diabetes prior to your surgery. If you have the Libre Pro CGM placed, your perioperative team will not be able to review your CGM data prior to surgery, and will not contact you with additional recommendations for how to improve control of your diabetes prior to your surgery.

Regardless of the group you are assigned to, you will proceed to have your surgery and recovery as you normally would, and receive the standard glucose checks (and subsequent treatment with insulin if needed) as you normally would as ordered by your surgical providers. It may be worn for up to 14 days maximum. This includes the amount of time it was worn between your preoperative visit and surgery day. The continuous glucose monitor will be removed prior to your discharge from the hospital after your surgery. If you have the Libre 2 CGM placed, research staff will be able to review your glucose data in realtime. If you have the Libre Pro CGM placed, research staff will be able to download your glucose data when your CGM is scanned on the day of surgery. The CGM will be removed by research staff prior to discharge.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for a maximum of 14 days. Enrolling in this study will not prolong your hospital stay.

You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the insertion of the continuous glucose monitor device we are studying include the discomfort of having the device placed on the back of the arm as this uses a small needle with the filament from the continuous glucose monitor is inserted into the subcutaneous fat on the back of the arm. It is common for participants to experience mild discomfort when the device is inserted. The discomfort is expected to last 1-2 seconds. Removal of the device is expected to have minimal discomfort that is mainly from the

adhesive used to keep the continuous glucose monitor in place for a maximum duration of 14 days. It is very uncommon to have prolonged discomfort with insertion or removal of the device. You may experience discomfort, bruising and/or bleeding where the needle is inserted with placement of the continuous glucose monitor. Occasionally some people become dizzy lightheaded or feel faint. Infection may occur on very rare occasions.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you are randomized to wear the Freestyle Libre 2 CGM, you may receive additional recommendations prior to surgery that may improve control of your diabetes prior to surgery. If you are randomized to wear the Freestyle Libre Pro CGM, you are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options: continue with usual standard of care during your hospitalization.

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

Device will be provided by the Wake Forest Clinical and Translational Science Institute and will not be charged to your insurance company.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to utilize the Freestyle Libre 2 to improve glucose management during the perioperative period; the results will be provided to the Food and Drug Administration and other federal and regulatory agencies as required.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is not sponsored.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management, at [redacted].

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Susan Vishneski, MD at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information and/or information we get from your medical about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes**:** name, age, sex, date of birth, type of diabetes, weight, and laboratory results.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records which will be kept for an indeterminate period of time. This authorization does not expire. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center. You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Susan R. Vishneski, MD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Susan R. Vishneski
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because new information becomes available, you had an unexpected reaction to the device, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Susan R. Vishneski, MD at [redacted], or a member of the research team at [redacted] at any time.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____

Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____

Date:_____ Time:_____ am pm