RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TYPE OF CONSENT
Main

TITLE
Continuous Monitoring Using a Smart Implantable Device (Persona IQ®) to Compare Medial Parapatellar vs. Subvastus Approaches in Early Post-Operative Total Knee Arthroplasty Recovery

SPONSOR
Northside Hospital, Inc.

INVESTIGATOR
Thomas L. Bradbury, Jr. , MD
Northside Hospital, Inc.
1000 Johnson Ferry Road NE
Atlanta, Georgia 30342

STUDY-RELATED PHONE NUMBER
(24 hours) 404-851-2300

INTRODUCTION AND PURPOSE OF STUDY

You are being asked to voluntarily participate in a research study. You do not have to participate if you do not want to. You are being asked to take part in this study because you are older than 18 years of age and planning on undergoing routine care primary total knee replacement. This research is being done to compare recovery patterns between two common surgical approaches used in total knee replacement:

- Medial Parapatellar (MPP): The traditional, widely used approach that involves going through the quadriceps muscle to access the knee joint.
- Subvastus (SV): A more technically complex approach that spares the quadriceps muscle, potentially allowing for improved initial recovery.

Prior to surgery, you will be randomized to receive one of the approaches, both routinely used for this operation. The goal of this study is to track recovery during the first 30 days after surgery using the Persona IQ® smart knee implant, which is United States Food & Drug Administration (FDA)-approved and collects continuous movement data from inside your knee.
You will be one of approximately 100-120 people involved in this research project.

DESCRIPTION OF PROCEDURE

Your participation in this study will begin prior to your total knee replacement surgery. You will be asked to keep your iPhone with you as often as possible during the two weeks before surgery so that it can record your daily step count. On the day of your surgery, a member of the research team will record the step count information from your iPhone Health application. If you also use an Apple Watch, the step count recorded by your watch may automatically be included in your iPhone Health data. You will undergo a routine total knee replacement with the Persona IQ® smart knee implant performed by your surgeon using either the MPP or SV approach.
The approach used during your surgery will be assigned based on chance, similar to flipping a coin. Your chance of receiving either treatment is equal.

The Persona IQ® smart knee, which tracks data about your knee function during recovery, will be implanted as a routine part of surgery. This device will continuously collect data as part of standard clinical care, and the data collected during the first 6 months after surgery will be used for this study. After surgery, you will complete several standard post-operative surveys. You may also be asked questions about your ability to perform daily tasks such as household chores or walking unassisted. All study-related procedures will occur alongside your standard clinical care and follow-up visits.

POSSIBLE RISKS/DISCOMFORT/SIDE EFFECTS

The study involves standard of care surgical procedures and carries no additional physical risk beyond routine clinical care. As with any study involving personal health information, there is a risk of a breach of confidentiality. However, all data will be stored and protected using secure digital platforms and password protection.

If you are injured during your participation in this study, medical care will be provided. You or your insurance will be billed in the usual manner for this care.

The risks and benefits of your primary total knee replacement will be discussed with you by your surgeon and you will receive a separate consent form for the surgery. Common risks include:

Frequent and most common side effects

- Mild knee stiffness
- Increased pain
- Swelling or inflammation
- Decreased range of motion
- Decreased progress

Less common/rare side effects

- Inability to work
- Risks to confidentiality of your health information

POSSIBLE BENEFITS

There are no direct additional benefits expected to you as a participant in this study. However, the results of this study may improve understanding of how different surgical approaches affect early recovery, potentially helping future patients and informing surgical practices and rehabilitation programs.

ALTERNATIVE PROCEDURES OR COURSES OF TREATMENT

Participation in this research study is completely voluntary. You decide whether or not to participate. If you choose not to participate, you may still receive your standard knee replacement surgery and post-operative care as usual. In that case, the surgeon will determine the surgical approach and implant type as part of routine clinical care. You may decline to participate without any penalty or loss of benefits.

COMPENSATION AND COSTS TO SUBJECT

You will not be paid for your participation and no additional costs are expected to you for activities related to the research study. The Personal IQ is part of standard care at Northside Hospital. You or your insurance will be responsible for the standard costs associated with your clinical care.

VOLUNTARY PARTICIPATION AND RIGHT TO WITHDRAW

Your participation in this study is voluntary. You have the right to choose not to participate or withdraw from the study at any time. Deciding not to participate or later withdrawing from the study will not change your ability to receive medical care. There is no penalty or loss of benefits if you choose not to participate. If you do not participate, there will be no change in your ability to receive medical care from your doctor or Northside Hospital, now or in the future. You will be informed of any significant new findings that may affect your treatment or your willingness to continue in the study.

Unless you specifically request to have all of your data removed from the study, researchers may include data that was collected prior to your withdrawal from the study in data analyses and publications.

STATEMENT OF NON-WAIVER

By signing this consent form, you have not waived any of your legal rights or released any party from liability for negligence.

NORTHSIDE HOSPITAL, INC.'S AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Efforts will be made to keep your personal information confidential, and procedures may include removing your name and other identifying information from data collected during the study to protect your privacy. However, we cannot guarantee total confidentiality.

Your personal health information will be used and disclosed to others for this research study. A decision to participate in this study means that you agree to the use and disclosure of your personal health information for the purposes explained in this consent form.

During the course of the study, the research team may use the following health information:

- Your past and present medical records
- Research records
- Records about phone calls made as part of this study
- Records about your study visit and information obtained through physical exams, laboratory tests, and imaging tests.

The following individuals or entities will have access to your personal health information as necessary to conduct this research study: Thomas Bradbury, MD, the principal investigator for the study, the research staff conducting the study and clinical staff involved in your care.

Your personal health information may also be disclosed to:

- Northside Hospital, Inc. and the Northside Hospital Central Research Department to monitor the conduct of the study. Your health information may be used and disclosed by Northside Hospital, Inc., its representatives, affiliates and personnel for research, quality assurance, and data analysis purposes.

- Representatives of government agencies including the Food and Drug Administration (FDA) or other agencies of the Department of Health and Human Services (DHHS) for research or regulatory purposes to monitor the conduct of the study.

- The Northside Hospital Institutional Review Board to review the research for purposes of human subjects protection.

The Northside Hospital Central Research Department may also permit these groups to come in to review your original medical records that are maintained by Northside Hospital so that they can monitor their research study. These recipients may not be required by health information privacy laws and regulations to maintain confidentiality of health information. There is the potential that your information may be re-disclosed by recipients identified in this section and that it will no longer be subject to protection under health information privacy laws and regulations.

Your right to access your health information used and disclosed for the study may be restricted as long as the research is in progress; however, your right to access will be reinstated upon completion of the research study.

Study records that identify you will be kept confidential as required by law. Except when required by law, you will not be identified by name, social security number, address, phone number, or any other direct personal identifier in the study records disclosed to outside individuals or institutions.

When such disclosures do occur, you will be assigned a unique code number. The key to the code will be kept under secure conditions by site staff. The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

By signing this consent form, you authorize the use and disclosure of your personal health information collected in connection with your participation in this study INDEFINITELY. Your information will only be used as outlined in this consent form and according to applicable law.

You have the right to revoke your authorization to use your personal health information. The revocation must be in writing and sent to the Research Program Director at:

Northside Hospital Central Research Department
1000 Johnson Ferry Road NE
Atlanta, GA 30342

If you revoke your authorization, it will not apply to prior uses or disclosures of your personal health information made in accordance with the purposes explained in this consent form. In addition, the sponsor (Northside Hospital, Inc.) may continue to use information that has already been disclosed to them.

If you refuse to provide authorization to use and disclose your personal health information for this study, the investigator may refuse to include you as a participant in this study.

Your right to access your health information used and disclosed for the study may be restricted as long as the research is in progress; however, your right to access will be reinstated upon completion of the research study.

STUDY CONTACT PERSON TO HAVE QUESTIONS ANSWERED

If you have further questions or want more information concerning the research study and/or research-related risks or injuries, you may contact Dr. Thomas Bradbury at (770) 292-6500 - 24-hour access at any time.

INSTITUTIONAL REVIEW BOARD REVIEW STATEMENT AND CONTACT PERSON

An Institutional Review Board (research review board) at Northside Hospital has reviewed this study in the context of certain federal regulations relating to experimentation involving human subjects. Approval of this study by the Northside Hospital Institutional Review Board (NSH IRB) is not an endorsement of this study or its outcome. If you have any questions or concerns

about this study or your rights as a research subject, you should contact the Chair of the Northside Hospital Institutional Review Board at 404-851-6848.

STATEMENT OF VOLUNTARY CONSENT

I have read all of the above or have heard it read to me. I have had the opportunity to ask questions about this study and my questions have been answered to my satisfaction. A signed copy of this consent form will be given to me. I hereby give my consent to participate in this study. I further authorize the use and disclosure of my personal health information for the purposes described in this consent form.

_____ _____

Subject (representative) signature Date Time

_____

Representative's authority to sign for the subject

_____ _____

Witness Signature Date Time

INVESTIGATOR STATEMENT OF INFORMED CONSENT PROCESS

I have explained to the person named above, the nature of the research described above. To the best of my knowledge, the person signing this consent form understands the nature, demands, benefits, and risks involved in participating in this study.

_____ _____

Investigator Signature (or designee) Date Time