CONSENT DATE: Stamped August 7, 2023.

OFFICIAL TITLE: Assessing Benefits of NIRAF Detection for Identifying Parathyroid Glands During Total Thyroidectomy

NCT05579782

EFFECTIVE

August 7th, 2023

MCW IRB

Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

VANDERBILT-NIRAF-THYROIDECTOMY: Assessing Benefits of Near Infrared Autofluorescence (NIRAF) Detection for Identifying Parathyroid Glands during Total Thyroidectomy

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Definitions

PTeye – a device to help the surgeon in locating a diseased parathyroid gland during surgery

Randomization – the group you are in is assigned by chance, like the flip of a coin

Purpose

This project is being done to determine if the PTeye truly benefits a patient undergoing surgery for thyroid disease or not.

Length

- You will be in this research project for about 6 months.
- After the thyroid surgery is finished, you will have usual follow-up visits according to routine care.

Procedures

You will be assigned to either of 2 groups by a method called randomization. Randomization means that the group you are in is assigned by chance, like the flip of a coin. Depending upon which group you have been assigned to, the PTeye may or may not be used during the operation.

List of visits:

- Surgery Visit
  - Total Number: 1
  - Total Time: approx. 6-8 hours
- Follow-up Visit(s)
  - Total Number: per usual routine care
  - Total Time: varies

Procedures that will occur at various visits:

Invasive Procedures

- Blood collection for routine laboratory tests

Non-invasive Procedures

- PTeye device to locate your thyroid gland before surgery

Risks

This is a brief list of the most commonly seen side effects. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

PTeye risks:

- If PTeye were to be used during your operation, the only known risk is that of an extra 5 minutes of anesthesia may be required, although not always. The study should not increase the risk of infection, as the probe that touches your tissue will be sterile and disposed after use.
- The PTeye device has been FDA-cleared for marketing for label-free intraoperative parathyroid gland identification during thyroid surgeries. The PTeye may be associated with unknown/unforeseen risks as with any other FDA-cleared medical devices used during surgical procedures.

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Benefits

We don't know if this project will help you. Your condition may get better but it could stay the same or even get worse.

My Other Options

You do not have to join this project. Your other options may include:

- Joining a different project
- Routine care for this condition
- Getting no treatment for this condition

If you have more questions about this project at any time, you can call Tracy Wang, MD, MPH at 414-805-6700.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you have thyroid disease and will be undergoing thyroid surgery.

A total of about 160 people are expected to participate in this research at the Medical College of Wisconsin/Froedtert Hospital.

The Director of the project is Tracy Wang, MD, MPH in the Department of Medicine. A research team works with Dr. Wang. You can ask who these people are.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you do not agree to join, or if you leave, you will not be penalized or lose any benefits that you had before starting the research project. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A research project is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the research procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS PROJECT BEING DONE?

Located closely to the thyroid gland are the parathyroid glands, which are important organs that regulate calcium levels in your body. Thus, it is essential for a surgeon to correctly identify this structure when performing a thyroid surgery. The Food and Drug Administration agency recently approved a device called PTeye for helping the surgeon to identify and preserve healthy parathyroid glands during surgery. By assisting the surgeon in correctly identifying parathyroid glands, this device may improve the quality of the operation performed on the patient.

This study will determine if the PTeye truly benefits a patient undergoing surgery for thyroid disease or not. The device consists of a sterile disposable stainless-steel fiber-optic probe, which will be used to touch the tissue in your neck and the surgeon will be immediately alerted by the device if the tissue is parathyroid or not.

We don’t know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information from this study will help us develop a better treatment for thyroid surgery in the future.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

STUDY DEVICE

In prior studies, we have found that you can tell the difference between different types of tissue based on how it responds to light, and this analysis will not bother or hurt the tissue. We have also found that parathyroid tissue responds to light in a unique way compared to other tissues in

the neck. This property of parathyroid gland forms the basis of how the PTeye device works and can possibly help surgeons in accurately identifying parathyroid glands during neck operations.

If PTeye is to be used during your operation, a sterile fiber-optic probe will be used to touch the tissue in your neck and shine light on it. Based on the light signal collected back from the tissue, PTeye will indicate to the surgeon if the tissue is parathyroid or not. The light sources in the device are of very low power and cause no known side effects to you. The time needed for testing tissues with the PTeye device will be less than 2 seconds. The whole study should add less than 5 minutes to your surgery. If PTeye will not to be used during your operation, the surgeon will perform the procedure as she/he usually would.

STUDY GROUPS

In order to determine if PTeye improves the quality of the surgery or not, you will be assigned to either of 2 groups by a method called randomization. Randomization means that the group you are in is assigned by chance, like the flip of a coin. Depending upon which group you have been assigned to, the PTeye may or may not be used during the operation.

STUDY PROCEDURES

The research staff on this study will have access to (i) information such as your age, race, gender, body mass index (without your name or personal information) (ii) reports on blood and/or biopsy tests taken before and after this surgery, (iii) medications taken before and after this surgery and (iv) details of hospital admissions after this surgery.

At her/his discretion, the surgeon will assess calcium and/or parathyroid hormone (PTH) levels in your blood in the post-operative period (within 24 hours after surgery) as per routine care. If the calcium and PTH levels are not normal after surgery, the surgeon will follow up these blood investigations during your routine first follow-up at clinic after surgery. As part of your routine medical care, if your calcium and PTH levels are still abnormal when followed up at the clinic, the surgeon may then again reassess your blood calcium and PTH levels up to as long as 6 months after the surgical procedure, to determine if they have eventually returned to normal levels or not.

B2. HOW LONG WILL I BE IN THE PROJECT?

After the thyroid surgery is finished, you will have usual follow-up visits according to routine care. We will continue collecting data from you for the study up to 6 months after your surgery.

B3. CAN I STOP BEING IN THE PROJECT?

You are free to withdraw from the project at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the research doctor.

The research doctor can tell you about the effects of stopping, and you and the research doctor can talk about what follow-up care would help you the most.

The research doctor or the sponsor may take you out of this project at any time. This would happen if:

- They think it is in your best interest.
- You do not follow the project rules.
- The whole project is stopped.

If this happens, the research doctor will tell you.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

There are risks to taking part in any research project. There is a risk that you may get assigned to the device that does not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet, from the device itself, or how it combines with other drugs you are taking. If we learn about new important side effects, we will tell you.

We watch everyone in the project for problems (side effects). **You need to tell the research doctor or a member of the research team immediately if you experience any problems, side effects, or changes in your health.** In an emergency, call 911.

C2. RISKS OF THE DEVICE

The research device itself may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.

If PTeye were to be used during your operation, the only known risk is that of an extra 5 minutes of anesthesia may be required, although not always. The study should not increase the risk of infection, as the probe that touches your tissue will be sterile and disposed after use.

The PTeye device has been FDA-cleared for marketing for label-free intraoperative parathyroid gland identification during thyroid surgeries. The PTeye may be associated with unknown/unforeseen risks as with any other FDA-cleared medical devices used during surgical procedures.

C3. OTHER RISKS OF THIS RESEARCH PROJECT

Other procedures that are part of the research also involve some risks:

Blood collection
Blood collection may cause some discomfort, bleeding, or bruising at the puncture site. A small blood crust or swelling may occur at this site. In rare cases, fainting or local infection may occur. If you feel discomfort during blood collection, please report this to the study doctor or staff at the time.

Privacy and Confidentiality
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The study team can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The study team will use the Certificate to resist any demands for information that would identify you

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

We don't know if this study will help you. Your condition may get better, but it could stay the same or even get worse. We hope the information from this study will help us develop better treatments for thyroid surgeries.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

Most of the medical care that you will receive in this project is considered routine care for your condition and would be recommended whether or not you join the project. Costs for routine care will be billed to you or your insurance carrier. For routine clinical care, you will be responsible for paying any copayment, coinsurance, or deductible that is required by your insurance carrier.

Activities / costs that are part of the project will not be billed to you or your insurance company. These are:

- PTeye device use

Some insurers will not pay for drugs, tests or hospitalization that are part of research, so check with your insurer before you join this project. If you have questions regarding costs, please contact Dr. Wang.

If you participate in this research, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

There is no payment for being in this project.

Sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. Neither Sponsor nor Dr. Wang will pay you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced from your health information/biospecimens.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no. If you do not join this project, your research doctor can discuss other healthcare choices with you.

Your other choices may include:

- Tyroid surgery without using the PTeye device
- Joining a different research project

The research doctor can explain both the possible benefits and the risks of other options that are available to you.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

If we learn any important new information about the device that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

When research data/biospecimens are collected and analyzed, there is the chance of finding something clinically relevant. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is required or appropriate).

The results from the data/biospecimens we collect in this research study are not the same quality as what you would receive as part of your health care, so you will not be informed of any clinically relevant research findings. The results of your research data/biospecimens will not be placed in your medical record.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Tracy Wang, MD, MPH, 414-805-6700

Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Tracy Wang, MD, MPH at 414-805-6700.
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); Versiti, Inc.; Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital; Froedtert West Bend Hospital; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information to be collected and used for this project is:

- Past and present medical records to document relevant pre-existing conditions
- Records about your study visits and results of tests done during the study
- Records about phone calls made as part of this research
- Research records

E2. Who will see the health information collected for this project?

The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.

If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

The research team may share your information with people who don't work at MCW/Froedtert Hospital because they planned, pay for, or work with us on this project. The federal Privacy Rule may no longer protect your health information once it leaves MCW/Froedtert Hospital. For this project, we plan to share information with those doctors, researchers or government representatives working with us on this project at the institutions or companies listed here:

- Florence Healthcare, Inc.
- Companies that fund the study;
- Government agencies in the U.S., such as the Food and Drug Administration (FDA), National Cancer Institute (NCI), and National Institutes of Health (NIH);
- Other federal and state agencies, such as the Office of Human Research Protections, (OHRP);
- Others required by law who monitor research

Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records.

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal identification is removed from your health information and/or biospecimens, the information and/or biospecimens may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information without any end-date in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Tracy Wang, MD, MPH at

Department of Surgery
Medical College of Wisconsin
8701 Watertown Plank Road
Milwaukee WI 53226

The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we will decide that you cannot continue to be part of the project. We may still use the information we have already collected.

E6. Access to records

You may not be able to see, or copy, your project-related health information until after the project has been completed; otherwise, it could affect the study.

F1. FOR MORE INFORMATION ABOUT THE PROJECT

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.

You can look up this project by referring to the ClinicalTrials.gov number (NCT04281875) or by asking the research team for a printed copy.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**
*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*