Evaluating Impact of Near Infrared Autofluorescence (NIRAF) Detection for Identifying Parathyroid Glands during Parathyroidectomy

NCT05022641

Date of IRB Approval: May 5, 2021

UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title: Evaluating Impact of Near Infrared Autofluorescence (NIRAF) Detection for Identifying Parathyroid Glands during Parathyroidectomy

Company or agency sponsoring the study: There is no sponsor for this study.
Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Paul Gauger**,** M.D., Department of Surgery, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains important information that will help you decide whether to join the study. Take the time to carefully review this information. You should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others such as your family, friends, or other doctors about joining this study. If you decide to join the study, you will be asked to sign this form before you can start study-related activities. Before you do, be sure you understand what the research study is about.

A research study is different from the regular medical care you receive from your doctor. Research studies hope to make discoveries and learn new information about diseases and how to treat them. You should consider the reasons why you might want to join a research study or why it is not the best decision for you at this time.

Research studies do not always offer the possibility of treating your disease or condition. Research studies also have different kinds of risks and risk levels, depending on the type of the study. You may also need to think about other requirements for being in the study. For example, some studies require you to travel to scheduled visits at the study site in Ann Arbor or elsewhere. This may require you to arrange travel, change work schedules, find child care, or make other plans. In your decision to participate in this study, consider all of these matters carefully.

This research is studying the use of a new device called PTeye in small numbers of people to learn about its efficacy in identifying parathyroid tissue in patients with primary hyperparathyroidism. Researchers want to understand how device performs at identifying parathyroid tissue. You are being asked to take part in this research study because you have parathyroid disease and will be undergoing parathyroid surgery. Parathyroid glands are important organs in your neck that regulate calcium levels in your body. Thus, it is essential for a surgeon to correctly identify this organ when performing parathyroid surgeries. A device called 'PTeye' was recently cleared for marketing by the Food and Drug Administration agency, to help the surgeon in locating a diseased parathyroid gland 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 parathyroid 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. Your health-related information including future laboratory

results will be collected for this research study.

This study involves a process called randomization. This means that whether or not the device is used on you in the study is not chosen by you or the researcher. The study design divides study participants into separate groups, based on chance (like the flip of a coin), to compare different treatments or procedures. If you decide to be in the study, you need to be comfortable not knowing which study group you will be in.

There can be risks associated with joining any research study. The type of risk may impact whether you decide to join the study. For this study, the only known risk is that an extra amount of anesthesia time (up to 5 minutes) may be required to use the PTeye during your surgery. The study should not increase the risk of infection, as the probe that touches your tissue will be sterile and disposed after use. There could be unforeseen risks from the device itself, though the PTeye has been cleared for marketing by the FDA for label-free intraoperative parathyroid gland identification during surgeries. More detailed information will be provided later in this document.

This study may offer some benefit to you now or others in the future. The study doctors hope that the results of this study will help them determine if a device such as PTeye can improve the quality of operations performed for parathyroid disease which would benefit patients by decreasing the time taken for surgery, reducing the number of biopsies performed during surgeries, preventing complications after a parathyroid operation and thus reducing overall healthcare costs. More information will be provided later in this document.

We expect the amount of time you will participate in the study will be 6-12months.

You can decide not to be in this study. Alternatives to joining this study include proceeding with parathyroid surgery without the use of PTeye.

Even if you decide to join the study now, you are free to leave at any time if you change your mind.

More information about this study continues in Section 2 of this document.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

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. 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 parathyroid disease or not.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled.

3.1 Who can take part in this study?

Patients can participate in this study if they are ≥ 18 years old and undergoing parathyroid surgery for either primary hyperparathyroidism or persistent primary hyperparathyroidism after prior failed parathyroid surgery. Patients are not eligible if they are <18 years old, pregnant, have concurrent thyroid disease requiring thyroidectomy or if they have a diagnosis of secondary or tertiary hyperparathyroidism. Those patients who could potentially will receive preoperative pregnancy testing, as is standard before general anesthesia. Any patients with positive pregnancy test results will not be included in the study.

3.2 How many people are expected to take part in this study?

160 total subjects at the University of Michigan (80 will have PTeye used and 80 will not).

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

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.' Depending upon which group you have been assigned to, the 'PTeye' may or may not be used during the operation. 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.

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. During your first routine follow-up at clinic (5 – 14 days after surgery), the surgeon will assess calcium and parathyroid hormone (PTH) levels in your blood as per

routine care. If the calcium and PTH levels are not normal after surgery, the surgeon will follow up these blood investigations. 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.

As a subject participating in this research study, you have certain responsibilities that may apply to this study, such as ensuring that you arrive at all of your scheduled appointments, get your bloodwork done on time, and report any adverse reactions you may have during the study.

Besides the information about the main study, the following information is specific to unspecified future use of identifiable data. We would also like your permission to keep some of your medical information collected in the main study, so that we may study it in future research. The future research may be similar to this study or may be completely different.

You can take part in the main study even if you decide not to let us keep medical information for future research.

If you give us your permission, we will use your medical information for future research. Even if you give us permission now to keep some of your medical information, you can change your mind later and ask us to destroy it. Keep in mind, however, that once we have analyzed your information, we may not be able to take the information out of our research.

We may share your medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your medical information with other researchers, we will not be able to get it back.

Future use of your identifiable data will be conducted in compliance with applicable regulatory requirements.

You will not find out the results of future research. Allowing us to do future research on your medical information will not benefit you directly.

With appropriate permissions, your collected information may also be shared with other researchers here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

4.2 How much of my time will be needed to take part in this study?
Your time required to participate will be exactly the same as if you were undergoing parathyroid surgery and not participating in the study. You will be seen in a preoperative visit, for your surgery, and at a postoperative visit, just as all parathyroid surgery patients. Your blood tests and results will be done at those appointments and during surgery. As part of routine care after parathyroid surgery, you may need further calcium and parathyroid hormone (PTH) blood draws if your levels remain abnormal at your postoperative visit. Your surgeon may need to reassess your levels up to 6 months after surgery to determine if they have returned to normal levels or not.

4.3 When will my participation in the study be over?
As above, your participation will end in the postoperative period, depending on your calcium and parathyroid hormone (PTH) results. Blood draws to monitor these levels will end at 6 months after surgery.

4.4 What will happen with my information and/or biospecimens used in this study?
With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?
The known or expected risks are:

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 cleared for marketing by the FDA for label-free intraoperative parathyroid gland identification during surgeries. However, there may still be associated risks that we do not know about the device at this time.

The researchers will try to minimize these risks by:
The researchers will ensure appropriate sterile technique during your surgery and will make all attempts to minimize the time added to your surgery while using the PTeye device.

Additionally, there may be a risk of loss to confidentiality or privacy. See Section 9 of this document for more information on how the study team will protect your confidentiality and privacy.

As with any research study, there may be additional risks that are unknown or unexpected.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Paul Gauger at 734-936-5738. If you cannot reach the research staff, please page the study doctor at 734-936-4000.

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?
Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?
You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study. The study doctors hope that the results of this study will help them determine if a device such as PTeye can improve the quality of operations performed for parathyroid disease and can benefit patients – decrease the time taken for surgery, reduce the number of biopsies performed during surgeries, prevent complications after a parathyroid operation and thus reduce overall healthcare costs.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?
Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?
If you do not participate in this study, you will have parathyroid surgery in the standard fashion, without the use of the PTeye device. You will also have standard postoperative follow up and laboratory blood draws.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?
You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?
No, there would not be any harm to you if you left the study before it is finished.

7.3 Could the researchers take me out of the study even if I want to continue to participate?
Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?
There are no costs or billing for this study.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will not be paid for your time spent taking part in this study.

8.3 Who could profit or financially benefit from the study results?
The company whose product is being studied:
Medtronic
Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study, and any sub-studies described in this document.

9.1 How will the researchers protect my information?
Confidentiality will be assured by limiting access to patient identifying data and using a coding system which will remove patient identifying information from the data. Data collected in this study will be stored on a password protected computer and data analyses will be performed without using patients' information.

Your normal postoperative test results will be available to and will be reviewed with you in your medical record.

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results and dental records
- Any records relating to condition, treatment received, and response to treatment
- Demographic information

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA) and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular UMHS medical record.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities. (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- 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: Paul Gauger
Mailing Address: 1500 E Medical Center Dr, SPC 5331, Taubman Center, Ann Arbor, MI 48103
Telephone: 734-936-5738

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800

Telephone: 734-763-4768 (For International Studies, include the appropriate calling codes.)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.
When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This signed and dated "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Sig-A

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with [NAME OF STUDY TEAM MEMBER OBTAINING CONSENT] _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-D

Consent to Collect for Unspecified Future Research

This project involves the option to allow the study team to keep your identifiable specimens/data for use in future research. I understand that it is my choice whether or not to allow future use of my specimens. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

_____ Yes, I agree to let the study team keep my specimens for future research.

_____ No, I do not agree to let the study team keep my specimens for future research.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Sig-G

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____