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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

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

Research Project Director:	Quan-Yang Duh, M.D., Professor of Surgery. Endocrine Surgery, [redacted]

Study summary

This study will assess whether using a new device to help identify the parathyroid glands has any clinical benefits. The FDA-approved device, the PTeye device uses near infrared autofluorescence (NIRAF) detection for identifying parathyroid glands (PGs) during parathyroidectomy (surgery to remove abnormal parathyroid glands). This study compares risks, benefits and outcomes in parathyroidectomy patients where NIRAF detection for parathyroid identification is either used or not.

Introduction

We are asking you to consider taking part in a research study being performed at UCSF. This study is partially sponsored by the National Institutes of Health (NIH).

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team. If you have any questions, you may ask your study doctor.

Why is this study being done?

You are being asked to take part in this research study because you have parathyroid disease and will be undergoing parathyroid surgery. The parathyroid gland is an important organ in your neck that regulates 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 approved by the Food and Drug Administration agency, for helping surgeons to locate a diseased parathyroid gland during surgery. The device consists of a sterile disposable stainless-steel fiber-optic probe, which is used to touch tissue, and alert the surgeon as to whether the tissue is parathyroid or not based on how the tissue responds to light. This analysis will not bother or hurt the tissue. 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..

How many people will take part in this study?

Approximately 110 participants will be enrolled for this study at UCSF.

What will happen if I take part in this research 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'. 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. 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. Whichever group you are in, your surgeon will use his or her clinical judgement to remove your abnormal parathyroid gland (or glands). All removed tissue will be sent to pathology for analysis.

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.

Costs to you if you take part in this study:

There is no cost to you for taking part in this study. There will be no additional required testing or clinic visits.

Side effects and risks that you can expect if you take part in this study:

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.

Risks that are not known:

The PTeye may be associated with unknown/unforeseen risks as with any other FDA-approved medical devices used during surgical procedures.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. Authorized representatives from the University of California or the National Institutes of Health may review your research data for the purpose of monitoring or managing the conduct of this study.

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Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help doctors learn more about the PTeye device, and it is hoped that this information will help in the treatment of future patients with hyperparathyroidism.

Other treatments you could get if you decide not to be in this study:

If you do not wish to take part in this research study, you will still have surgery for your parathyroid gland as planned with your doctor. Your doctor will discuss all treatment options with you. You can decide not to take part in this study and it will not affect the care your doctor gives you.

Will I be paid for taking part in this study?

You will not be paid for your time spent taking part in this study.

Reasons why the study doctor may take you out of this study:

The study doctor will withdraw you from the study if you have any problems during the surgery that the doctor did not expect or if your health changes while you are in the study.

Can I stop being in this study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the PTeye device can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctor, Dr. Quan-Yang Duh, if you feel that you have been injured because of taking part in this study. You can tell the doctor in person or call him/her [redacted].

Treatment and Compensation for Injury:

If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

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Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor, Dr. Quan-Yang Duh [redacted].

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814

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.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

_____ _____

Date Participant's Signature for Consent

_____ _____

Date Person Obtaining Consent