Advanced Angle-Resolved Low Coherence Interferometry (a/LCI) Systems for Improved Clinical Utility: An a/LCI-Optical Coherence Tomography (OCT) Pilot Study

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University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 31May2022
IRB Study # 17-3037
Title of Study: Advanced a/LCI Systems for Improved Clinical Utility: An Optical Coherence Tomography (OCT) Pilot Study (OCT Pilot)
Principal Investigator: Nicholas Shaheen
Principal Investigator Department: Medicine-Gastroenterology
Principal Investigator Phone number: [redacted]
Principal Investigator Email Address: [redacted]
Funding Source and/or Sponsor: Duke University; National Cancer Institute

Study Contact Telephone Number: [redacted]
Study Contact Email: [redacted]

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to test a new investigational device developed by investigators at Duke University to detect unwanted pre-cancerous tissue in the esophagus (Barret's Esophagus). Investigational device means it is not yet approved for use in humans and is still being tested in research studies to determine its effectiveness and safety. The device uses light to detect changes in cells of the esophagus (food tube). This research is being done to collect information on the operating characteristics of the device to prepare it for use in a larger scale study.

You are being asked to be in the study because you are presenting to UNC hospitals for an upper endoscopy for your clinical care.

Are there any reasons you should not be in this study?
You should not be in this study if you:

1. Are younger than 18 years or older than 80 years
2. Are not able to read, comprehend, and understand this document.
3. Have had prior surgery of your esophagus other than uncomplicated nissen fundoplication (anti-reflux surgical procedure)
4. Are pregnant
5. Have a history of esophageal stricture (narrowing of your esophagus) or prior esophageal dilation (procedure to stretch the esophagus)

You should not have research biopsies collected if you:

6. Have an uncontrolled coagulopathy (bleeding disorder)

How many people will take part in this study?
A total of approximately 200 people at UNC will take part in this study.

How long will your part in this study last?
Your participation in this study will last about 7 days. This includes time to review this consent form, as well as time collecting data and administering the investigational device during your already scheduled standard of care upper endoscopy (a procedure where a tube with light and camera on the end are inserted into your esophagus). You will be contacted 7 days after the procedure to see how you are doing. Your participation is complete when you've completed the 7 day follow-up.

What will happen if you take part in the study?
If you agree to take part in the study, then you will be asked to sign this consent form. If you are a female with reproductive potential, then you will complete a urine pregnancy test paid for by the study. We will collect relevant information from your medical record for this study related to your age and information about any esophageal conditions you may have (acid reflux, Barrett's Esophagus, etc.).

You will then undergo your upper endoscopy that has already been scheduled as part of your clinical care. During the upper endoscopy, and prior to taking any clinically indicated biopsies (small tissue samples), an investigational device developed by investigators will be administered.

The investigational device will be attached to the end of the endoscope (a tube with a camera and light on the end) and passed with the endoscope into your esophagus. This method of attaching a probe to the end of an endoscope is common practice during an upper endoscopy. However, in this study the probe is investigational, meaning it is not yet approved for use in humans.

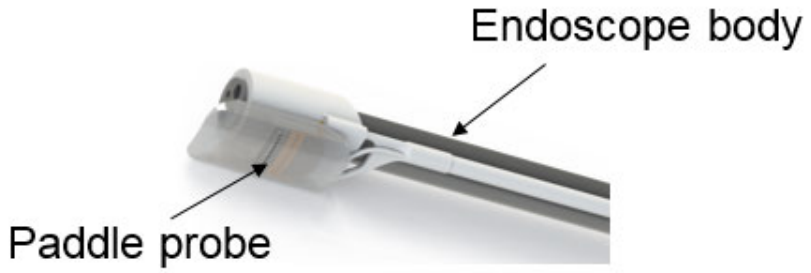

Figure 1: 3D concept rendering of probe paddle attached to endoscope

The optical probe will make contact with the lining (epithelium) of your esophagus and will transmit light against it, similar to holding a flashlight against your skin. The device uses information from the light to take images and collect data about the lining of your esophagus. It is similar to an ultrasound, but instead of bouncing sound waves off of the object, it bounces light waves. These light waves are collected by the device to help us understand the type of tissues below the probe. These images and data will be used in this study and stored indefinitely.

Pictures of your esophagus will also be taken for this study. If biopsies are taken for your clinical care, then results from those biopsies will be used in this study. Your clinical biopsies are stored at UNC as part of your clinical care. Slides (small slices of tissue) from your stored clinical biopsies may also be requested and used in this study. In addition, up to 10 study-specific biopsies may be taken and sent to pathology for analysis. You will be asked to review a separate consent form with information about the storage and future use of these samples.

You will be contacted via phone 7 days after the procedure to see how you are doing. Your participation in this study is complete after completion of the 7 day follow-up contact.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. You will not benefit personally from being in this research study.

What are the possible risks or discomforts involved from being in this study?

There are no known complications due to application of the OCT and aLCI imaging techniques. Although the technique is not invasive, the probe itself will come in contact with the lining of your esophagus. For that reason, there is a theoretical risk of infection. To guard against this, the probe will be disinfected between uses using acceptable disinfection methods. To date, there have been no adverse effects reported from exposure to the spectrum of light used in this device. There is no risk of radiation from this device because it uses only light waves.

Because the device is administered in conjunction with an upper endoscopy, there are a number of potential risks associated with the endoscopy that will be reviewed with you as part of your clinical care. There are also expected adverse events you may experience as a result of the endoscopy in which the device may not be able to be ruled out. These events include but are not limited to: throat irritation including scratchy or sore throat, esophageal pain, bloating, bleeding or tearing (perforation) of tissue in the esophagus, allergic reaction to the medication used for the endoscopy procedure (nausea, vomiting, fever, hypoxia (reduction in oxygen to tissues),

pneumonia, adverse drug reactions, urine retention, clumsiness, drowsiness, blurred vision, and death), or aspiration of contents into the lungs. These are risks and discomforts associated with the endoscopy procedure itself, regardless of whether you are in this study.

Serious risk of endoscopic biopsies are very uncommon in subjects without known bleeding disorders and in those who do not regularly take blood thinning medications (such as aspirin, nonsteroidal anti-inflammatory medications, Coumadin (warfarin), Plavix, Lovenox, Eliquis, Pradaxa, Xarelto, heparin, and low molecular weight heparin. This is because the biopsies are very small (2-3 mm) and are obtained with blunt (not pointy) tipped forceps under direct vision of the doctor performing your endoscopy. Possible serious complications include excess bleeding from the biopsy sites causing the blood pressure to drop and/or the need for blood transfusion. Even rarer is the risk of perforation (a tear in your esophagus or stomach) and infection. More common, but not serious, is minor bleeding which requires no treatment or responds to treatment with oral antacids. The risk of bleeding secondary to endoscopic biopsies is less than 1/1,000 and there is an even smaller risk of perforation (creating a hole or tear in your esophagus) or infection.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

Pregnancy tests will be done on all females who might be able to get pregnant at the start of the study. Pregnancy tests will be paid for by the study.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?

Electronic research records will be stored on secure encrypted computers and paper records will be maintained in locked filing cabinets. Access to all records for this study (paper and electronic) will be limited to research personnel. In addition, you will be assigned a unique identifier (code) that does not contain any protected health information. One master list linking you to your code will be maintained separately from the analyzed research data. Some of your protected health information will be used in this research study and stored with the research data.

Participants will not be identified in any report or publication about this study. Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.

A copy of this consent form will go in to your medical record. This will allow the doctors caring for you to know what study medications or tests you may be receiving as a part of the study and know how to take care of you if you have other health problems or needs during the study.

What is a Certificate of Confidentiality?
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

No voluntary disclosure will be made.

What will happen if you are injured by this research?
All research involves a chance that something bad might happen to you. This may include the risk of personal injury. In spite of all safety measures, you might develop a reaction or injury from being in this study. If such problems occur, the researchers will help you get medical care, but any costs for the medical care will be billed to you and/or your insurance company. The University of North Carolina at Chapel Hill has not set aside funds to pay you for any such reactions or injuries, or for the related medical care. You do not give up any of your legal rights by signing this form.

What if you want to stop before your part in the study is complete?
You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
You will not receive anything for taking part in this study.

Will it cost you anything to be in this study?
It will not cost you anything to be in this study. Administration of the device may increase the length of your procedure time. If this occurs, then the study will pay for the additional procedure time.

Who is sponsoring this study?
This research is funded by the National Cancer Institute. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study, complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at [redacted] or by email to [redacted].

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

I voluntarily agree to participate in this research study and consent to (please **initial** on each line as appropriate):

_____ Device administration and collection of slides from clinical biopsies.

_____ Collection of research biopsies (up to 10 may be taken).

_____ _____
Signature of Research Participant Date

_____
Printed Name of Research Participant

_____ _____
Signature of Research Team Member Obtaining Consent Date

_____
Printed Name of Research Team Member Obtaining Consent