Jefferson Office of Human Research
Informed Consent OHR-8
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Department: Department of Internal Medicine/Division of Gastroenterology

Principal Investigator: Anand Kumar MD MPH

Study Title: Closure of mucosal and submucosal defects in the gastrointestinal tract using the novel X-Tack endoscopic suturing device

Lay Title: Closure of defects with the X-Tack endoscopic suturing device

General Information Section

Informed Consent

You are being asked to take part in a research study. Research is different from standard medical care, and is done to learn something new.

Please read on to find out:

- The purpose of this research.
- How this research is different from standard medical care.
- The procedures and the device involved.
- The risks.
- The possible benefits.
- The alternatives to taking part in this research.

You will have the opportunity to discuss this study with the research personnel. Use this information to decide if you want to take part in this research. This process is called informed consent.

Voluntary Participation

You do not have to take part in this research. It is your choice whether or not you want to take part. If you choose not to take part or choose to stop taking part at any time, there will be no penalty or loss of benefits that you would normally get.

Purpose

The purpose of this research is to determine whether a new device for suturing in the gastrointestinal tract is better (safer and more effective) than the current standard device for suturing.

How this Research is Different from Standard Medical Care

The new device being examined in this study is FDA-cleared for the suturing of mucosal defects (injury to the wall of the gastrointestinal tract left behind after a lesion is removed) or fistulas (abnormal connections in the gastrointestinal tract,) but has not yet been compared to the current standard device.

Number of Participants

About 50 people will take part in this research and Jefferson and about 50 in the whole study.

Inclusion criteria: Patients over 18 years of age who are having a defect closed with endoscopic sutures (stiches.)
Exclusion criteria: Blood clotting disorders, use of blood thinner medications, low blood pressure or fast heart rate, pregnancy

Duration

You will be in this research study during your procedure. You will receive a phone call 2-3 days after your procedure. Your health information collected during the study will be stored indefinitely.

Procedures and Risks

It is important that you know the procedures and risks involved in this research. These will be discussed with you and are included in detail later in this form. Review the information carefully when making your decision to take part in this research.

Possible Benefits

You may or may not personally benefit from taking part in this research, but the knowledge gained from the research may benefit others.

Alternatives to Taking Part in this Research

You have other options than taking part in this study. The alternative to being in this study is to not take part. This will not change your medical care, and your procedure will still be performed.

Costs

You may have costs for participating in this study. This is discussed in detail later in this form.

Payment

You will not be paid for taking part in this study. If this research or the information or specimens you provide result in commercial profit, you will not receive any money from that profit.

Ending Study Early

There are a number of reasons you may decide or be asked to stop the study early (example: medical issues). You may also have to stop the study early even if you do not want to. You and the research personnel will discuss the reason if this becomes necessary. If you do leave the study early, you may be asked to complete some of the procedures described in this form.

New Information

New information may come out during this study. You will be given any new information that could change your decision to take part. You may ask to see the information collected about you, but not until the entire study is complete. If in the future we learn information that will affect your health at that point in time, you will be given any research results that could affect your health. This is unlikely to happen.

Detailed Information Section

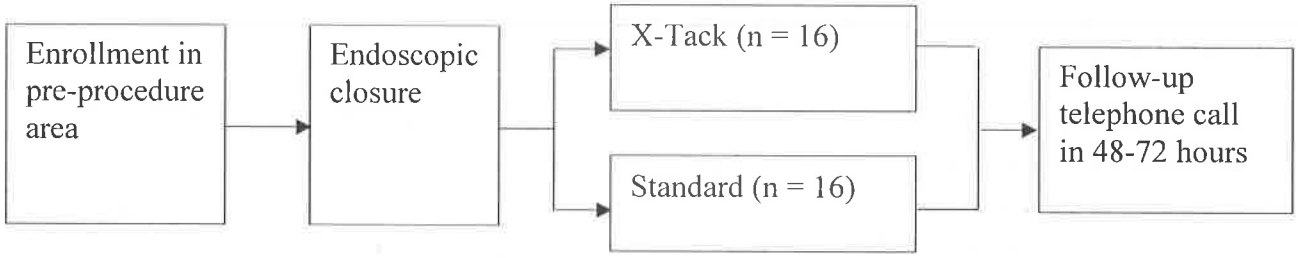
Drugs/Devices

The devices used in this study are described below:
Endoscope (flexible camera used to get to your lesion or fistula,) electrosurgical knife (a special device with a small needle that conducts electricity and acts as a knife when activated,) endoscopic clips (small metal clips placed with the endoscope used to close defects or holes that dislodge on their own after several weeks,) electrosurgical snares (loops of wire that can conduct an electrical current and are used to remove abnormal tissue,) Overstitch endoscopic suturing device (a device that is mounted on the endoscope and allows your doctor to place stitches with the endoscope.) All of the above devices are standard care. The study device is the X-Tack endoscopic suturing device, which also allows your doctor to place stitches with an endoscope but is mounted on the scope without having to remove it from the patient. You will either be

randomly assigned to the standard group or the X-Tack group. You are equally likely to be chosen for either group.

Procedures

While you are in this study, you will have one of two techniques performed during your endoscopy which are described below. During your endoscopy, you will be randomized to one technique or the other. Please note that additional tests and procedures may be needed to check on your health condition, including blood tests, imaging tests or additional endoscopic procedures.



Name of procedure #1 (half of patients): Standard closure

Description: The endoscope will be advanced to a target site. When it is time to close the target site, the endoscope will be removed and the Overstitch device will be mounted on the endoscope. The endoscope will then be reintroduced. The Overstitch device will be used to place stitches around the margins of the target site, and then the stitches will be cinched tight. After the defect is closed, your doctor will inspect the area to make sure that the stitches are well-positioned.

Risks: Risks of closure with the Overstitch include failed closure of the target and very rarely bleeding, infection, or a tear/perforation of the gastrointestinal tract.

Name of procedure #2 (half of patients): X-Tack closure

Description: The endoscope will be advanced to a target site. The X-Tack system will be introduced through a channel in the endoscope. The X-Tack system will be used to close the defect by applying tacks at the edges of the defect and then using a stitch to cinch them together. After the defect is closed, your doctor will inspect the area to make sure that the tacks are well-positioned. The tacks are designed to fall off after several weeks.

Risks: The risks of X-Tack closure are anticipated to be identical to those of Overstitch closure, listed above, though the X-Tack device is newer and less data is available.

Risks

Taking part in this study involves certain risks. The risks are the risks of performing endoscopic closure of a fistula or defect, whether or not you are participating in this study. Both the techniques being studied are anticipated to have similar risks. There may also be risks that are not known at this time. If you have any medical issues during this study, call the appropriate number in the contacts section of this form.

Risks of endoscopic suturing using either the X-Tack or the Overstitch device include bleeding, infection, perforation, or failure of closure of the target defect.

Reproductive Risks

Pregnant women are excluded from study participation.

Costs

You may have costs for participating in this study, though no additional costs are anticipated to be associated with the study. We anticipate that your insurance will cover this device as part of your procedure. There won't be any difference in costs whether you are in one study group of the other. There won't be any difference in costs if you are in the study or not.

You may be responsible for other costs. There is no plan to pay you for lost wages, lost time from work, personal discomfort, or for injuries or problems related to your underlying medical condition(s). If you receive a bill that you think is wrong, please contact the research personnel. You will be responsible to pay for your travel to and from the study site and other out-of-pocket expenses such as parking.

Research-Related Injury

There is a possibility that you could have research-related injury, which is an illness or an injury that is directly caused by the study device or a study procedure. If you have a research-related injury, we will offer you reasonable and necessary care to treat injuries directly resulting from taking part in this research. Neither Jefferson nor the study will pay for costs associated with treatment of research-related injury or illness. These costs may be billed to your insurance. In addition, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. There are no plans for Jefferson to pay you or give you other compensation for the injury. If you think you have been injured as a result of taking part in this research study, tell the research personnel as soon as possible. Please see the contact information in this consent form.

Disclosure of Financial Interest

The study group has no financial interest with the company that produces the study device. There is no financial benefit either for the participant (you,) the investigators, or the institution.

Privacy and Confidentiality: HIPAA Authorization

Information will be collected about you for this study. The information will be seen by the people involved with this research. Steps will be taken to protect your identity. But the information collected about you can never be 100% secure.

HIPAA (Health Insurance Portability and Accountability Act) – This is the law that protects your personal health information.

To do this study, we need to collect, use, and share your personal health information. This form will explain why your information is being collected, what information will be collected, and who will have access to it. By signing, you are giving us permission to use your information as described in this form.

We are committed to respecting your privacy and to keeping your personal health information confidential. Your personal health information includes the information in your health care records and information that can identify you. For example, personal information may include your name, address, phone number, social security number, and medical information. The personal health information that may be collected, used, and shared for this research includes:

- Information from your medical records
- Demographic information such as name, gender, birth date, ethnicity, medical history, and health care providers
- Physical examinations, procedures, tests, labs, your medical conditions, and medications you use
- Information collected about any research related injury
- Information about mental health, sexually transmitted diseases, HIV, AIDS, drug and alcohol use, genetic test results, and other sensitive information
- Photos and video recordings from the study procedure

Your personal information will be used by and shared with the following:

- Personnel at Thomas Jefferson University and its affiliates for the purpose of this research
- Institutional Review Boards (ethics committees that review research)
- Health insurance providers

- Government Agencies like the Food and Drug Administration (FDA)
- Groups monitoring the safety of the study such as a data and safety monitoring committee
- Others as required by law

When your personal information is provided to some of the people listed, it may no longer be protected under the HIPAA privacy law. You can see your health care records at any time. However, generally you will not be able to see your study records or the study results until the study is completed. A copy of this signed form, information about this study, and the results of any study test or procedure may be included in your health records which may be seen by your insurance company and your health care providers.

This authorization does not have an expiration date. Please inform the investigator in writing if you want to end your permission to collect information/samples. Please note that anything already collected will still be used and you may not be able to continue in this study.

The information from this study may be published in scientific journals or presented at scientific meetings, but you will not be personally identified.

A description of this study will be available on http://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.

Contacts

If you are having a medical emergency, call 911 or go directly to an emergency room. You should let emergency personnel or providers know that you are taking part in this study.

For Questions About:	Person or Office	Contact Information
The Study or Research Related Injury	Main Investigator: Anand Kumar MD MPH	215-955-8900
If you need to contact someone other than the study personnel about a concern or your rights as a research subject	Jefferson Center City Institutional Review Board (Ethics Committee)	215-503-0203 215-503-8966 215-955-4239

Signatures

Patient/Subject: By signing this form, you are agreeing that:

- You were given the opportunity to read this form.
- All of the information in this form was discussed with you by an investigator or other research personnel to your satisfaction.
- All your questions have been answered to your satisfaction.
- You were not pressured and you voluntarily agree to take part in this research.

_____	_____	_____
Your Name	Your **Signature**	Date

_____	_____	_____
Name of Person Obtaining/ Assisting with Consent	Signature of Person Obtaining/ Assisting with Consent	Date

The **physician investigator's** signature certifies that s/he **personally** provided the study participant with a description of the study, study procedures, risks, benefits and alternatives to participation.

_____	_____	_____
Name of Investigator	Signature of Investigator	Date

☐ **Copy of Signed and Dated Consent Form Given to the Subject/Parent/LAR**

As Per University Counsel - Do Not Sign This Consent Form After 4/7/22

Optional Teach-Back Questions – These questions can be asked to help ensure that the patient understands the study.

☐ Check this box if these questions were reviewed with the patient.

We have gone over a lot of information. I would like to ask you a few questions to make sure I have done a good job explaining the study to you.

1. In your own words, please answer these questions about this study:
    a. Why are we doing this study (what are we trying to learn)?
    b. What things (including tests and procedures) will you have to do in this study?
    c. What are some of the risks of being in this study?
    d. What is the benefit of being in this study?
    e. How will being in this study be different than usual medical care?
    f. How long will you be in this study?
2. Taking part in this study is voluntary. What does that mean to you?
    a. If you don't want to be in this study, what are your other choices?
    b. What will happen if you chose not to be in this study?
3. What will we do to make sure your information remains confidential?
4. What other questions do you have about this study?