Version #2
Date Submitted: March 8th, 2019

The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Single Blinded Non-inferiority Registry Based Randomized Control Trial Comparing Transfascial Sutures for Mesh Fixation to No Mesh Fixation for Open Retromuscular Repairs
Principal Investigator: Ajita S. Prabhu, MD (216) 444-4790

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you are scheduled for an abdominal wall hernia repair at our institute. The purpose of this study is to examine which mesh fixation technique results in better recovery for you.

You will be asked to fill a questionnaire during your preoperative evaluations, and on every follow up visit scheduled as part of your routine medical care.

Your participation in the research will last about 1 year.

More detailed information can be found under the section labeled: "Information on the Research."

Why might you choose not to participate in this research study?

Currently, some surgeons use sutures going through the abdominal wall for mesh fixation, and some don't. It is not known whether one technique provides better recovery after surgery. If you take part in the study, neither you nor your doctor will choose which method of fixation will be used during surgery.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?

We hope the information learned from this study will benefit medical science and provide information which may help improve the field of abdominal wall hernia surgery.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

Your ventral hernia requires the use of mesh for repair. When we place the mesh to cover your hernia, sutures that go through your abdominal wall are placed to fixate the mesh. However, whether these sutures provide benefit to your repair is not clear. Patients have reported that these sutures cause pain and eliminating their use might mean less pain after your operation, and quicker recovery. There is currently no evidence that either fixation or no fixation is better, which is why we are conducting this study.

How Many People Will Take Part in this Study?

Approximately 325 patients will be enrolled in this study at the Cleveland Clinic.

What is involved if you decide to take part in this research study?

Summary

If you agree to be in this study, you will be asked to sign this consent form. Your doctor will conduct the clinic visit as usual, and you will be asked to fill standard of care questionnaires assessing how the hernia affects your quality of life, as well as the pain around the site of the hernia. You will receive routine preoperative care, which will be personalized for each patient. This routine care is not part of the study. After your operation, you will follow up with your doctor as required, with 1 visit within 30 days, and another at one year. The doctor will conduct their routine post-operative care. Additionally, at each follow up, you will be asked again to fill a questionnaire evaluating your quality of life and pain.

Randomization

If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. This process is called randomization. This means that half of

the people in this study will have their mesh fixated with sutures that go through the abdominal wall and half of the people in this study will not receive these sutures. You will not know which study group you are randomized to until you complete the last study visit at 1 year. However, this information can be obtained if you have a medical emergency. Randomization will occur at the time of surgery. More precisely, randomization will occur at the moment your surgeon will place the mesh for your hernia repair.

Preoperative Visit

This will be your first meeting with your surgeon. During this visit, your surgeon will evaluate you for a ventral hernia and determine if you are a surgical candidate for ventral hernia repair. If your surgeon believes that you are a candidate for ventral hernia repair and that you meet the criteria for this study, he/she will discuss this will you. You will be given this informed consent document and any questions that you have related to this study will be answered. Basic information about your health will be collected and physical examination will be performed. These are consistent with standard of care. As part of this study, you will be asked to fill out a questionnaires related to your quality of life and current pain.

Day of Surgery

Your surgery will be performed in the usual manner, independent of your participation or not in this study. During the operation, you will be randomized to receive either no mesh fixation or mesh fixation with sutures going through the abdominal wall. As part of the study your doctor will collect information about your hernia and your surgery, such as the size of the ventral hernia, how long the surgery took, how much blood you lost during the surgery, antibiotics and IV fluids that are given, and how the ventral hernia was repaired. While this information is standard of care, it will also be used for study purposed.

Follow-Up

You will be given instructions to return to the physician's clinic to be examined by the study doctor at one month and 12 months following your surgery. This time period for follow-up is standard of care. You will have your incisions and wounds evaluated and examined for general health and hernia recurrence. You will be asked about any medications you are taking and about any problems you may have had with your ventral hernia repair. Information about any admissions to the hospital or any subsequent procedures that may have been performed during this time will be collected. In addition to standard of care procedures, you will be asked to complete the same surveys that you filled out prior to surgery at each of these visits. You will be informed how your mesh was fixated at the time of your 12 month follow-up appointment.

If at any time throughout the study period a ventral hernia recurrence is suspected clinically, then an abdominal CT scan will be performed to objectively evaluate the repair as standard of care dictates. All additional procedures, interventions, and adverse events will be collected throughout the final visit at 12 months postoperatively. The entire length of your active participation in this study will be for approximately 12 months following your hernia is repaired. In case you are not able to attend personally to your follow-up visit due to any reason, you have the option to follow-up with your surgeon using the Cleveland Clinic platform for Virtual Visits. The information from follow-up visits originated from this modality will also be used for this

study. In case you are not able to have your visit with the surgeon 12 months after the surgery due to any reason, we will contact you over the telephone where you will be able to answer the same surveys.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

You do not have to take part in this study if you do not want to participate or your feel uncomfortable with any part of the aforementioned process. Your choice to participate or not will have no impact on the clinical care you will receive from your doctor. Should you decide to take part and later change your mind, you can do so at any time. Again, withdrawing from this research study will have no impact on the clinical care you will receive from your doctor.

3. RISKS

What are the risks of participating in the research study?

Questionnaires: It is possible that some of the questions may be upsetting or you may feel uncomfortable answering them. If you do not wish to answer a question or participate in a portion of the non-invasive testing, we will skip that portion of the study.

Personal Health Information: There is a small risk to the confidentiality of your data. Safeguards are in place to protect your information. Data will be stored on a password-protected computer at Cleveland Clinic that is accessible only to the study staff.

4. BENEFITS

What are possible benefits of participating in the research?

There is no personal benefit to you by participating in this research study. The knowledge to be gained from this research may be beneficial for other patients, society or science.

5. COSTS

Are there any costs to you if you participate in this study?

There will be no additional costs to you as a result of taking part in this study. However, routine medical care for your condition (the care you would receive whether or not you were in this study) will be charged to you and/or your insurance company. You will be responsible for any co-payments and deductibles that are standard for your insurance coverage.

6. PAYMENT

Are there any payments to you if you participate in this study?

There are no payments to you should you decide to participate in this study as all care is routine and standard of care for patients with a ventral hernia.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event that you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct, or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic has rules and procedures to protect information about you. Federal and State Laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study, and personal identifying information including your name, address, date of birth, and other identifying information. This information will be used for the stated purpose of the study.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These included people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff. If you agree, your personal physician may be informed of your participation in the study.

People outside of Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration) and safety monitors. Cleveland Clinic will do our best to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic. However, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information. However, you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Ajita S. Prabhu MD, 9500 Euclid Avenue,

Cleveland, Ohio 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials

A description of this clinical trial 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 the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions, concerns, or complaints about the research or develop a research-related problem, contact Ajita S. Prabhu, MD at (216) 445-3441 during regular business hours (8am-5pm). After hours, please call the clinic operator at (216) 444-4790 or (800) 223-2273 and ask for the General Surgery resident on call. If you have questions about your rights as a research subject, you may contact the local Cleveland Clinic Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

You may refuse to be in or remove yourself from the study at any time without providing reason and this will not affect the standard of care you receive. To withdraw from the study, tell the principal investigator you no longer want to participate by contacting Ajita S. Prabhu, MD at (216) 444-4790.

If you choose to withdraw from the study, you will be followed based on standard of care at your institution. The investigator can remove you from the study without your approval. Possible reasons could be if participation appears to be medically harmful to you, if it is discovered that you do not meet eligibility requirements, or if the study is cancelled.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____
Printed name of Participant

_____ _____
Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____
Printed name of person obtaining consent

_____ _____
Signature of person obtaining consent Date