The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study Title: Registry Based, Randomized Controlled Trial Comparing Laparoscopic vs. Robotic Ventral Hernia Repair with Intraperitoneal Onlay Mesh (IPOM)

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You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**
- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at anytime.**

1. INFORMATION ON THE RESEARCH

Why are you being asked to take part in this research?
You are being asked to participate in a clinical research study because you are scheduled to undergo repair of your ventral (abdominal) hernia as part of your needed medical care.

Why is the research study being done?
There are currently several approaches to the repair of ventral hernias. When a ventral hernia is considered eligible to be repaired through a minimally invasive approach, the procedure can be done with laparoscopy (through insertion of cameras and instruments through small incisions in the abdomen) or with the assistance of robotics (using instruments and cameras that are controlled by robotic arms). Nevertheless, there remains little data comparing the outcomes of the laparoscopic ventral hernia repair and the robotic ventral hernia repair. The goal of this research is to compare pain levels after the surgeries, cost and hernia recurrence rates among patients operated on with a laparoscopic or robotic approach for ventral hernia repair.

How many people will take part in this study?
Approximately 74 patients will take part in this study.

What is involved if you decide to take part in this research study?
At this study visit, the doctor will ask about your past medical and surgical history and any medications you are taking, and you will have a brief physical examination. If you qualify for study participation, your doctor will discuss that with you. You will receive routine preoperative care and postoperative care, which will be personalized for each patient. This routine care is not part of the study.

If you agree to take part in this study, your active participation in this study will last for 12 months and will involve one preoperative evaluation visit (current visit), one operative procedure visit, answer to two telephone interviews assessing your level of pain (on the 1st and 7th postoperative days), and 2 follow-up visits. Except by the phone interviews performed on the 1st and 7th postoperative days, all the other procedures are standard of care and are anticipated to occur despite your participation in this study.

Preoperative Visit

If you agree to take part in this study, you will have screening assessments completed, and the study staff will collect additional information such as your gender, age, height, weight, your medical and surgical history, and information relating to your current ventral hernia. You will be asked to fill out baseline questionnaires that reflect the current pain level related to your ventral hernia, and your perception of quality of life at this appointment. The questionnaires will take approximately 5 minutes to complete.

Randomization

If you agree to take part 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 ventral hernia repaired laparoscopically and half of the people in this study will have their ventral hernia repaired robotically. Randomization will occur at the time of enrollment in the study during your preoperative evaluation. The operation performed (Ventral Hernia Repair with Intraperitoneal Onlay Mesh – IPOM) will be the same in both groups. The only difference is the platform that will be used to perform the operation (laparoscopic or robotic). You will not know how your ventral hernia will be repaired until the completion of the study. However, this information can be obtained if you have a medical emergency.

Day of Surgery

Your surgery will be performed in the usual manner based on your assigned surgical approach. As part of the study, your doctor will collect information about your hernia or your surgery such as the type of ventral hernia, the size of your ventral hernia, how long the surgery took, and how a ventral hernia was repaired. After the operation, you will receive routine postoperative care, including standard pain management, which is not part of this study. At the same day of the operation, when you are considered to be awake and no longer under the effect of anesthesia, you will be asked to rate your current pain level on a scale from 0 to 10.

After discharge – Postoperative day 1 and 7

Similar assessments to your pain level will be performed either in person if you are still hospitalized, or via telephone interview if you have already been discharged. You will be asked to rate your current pain level on a scale from 0 to 10.

Follow Up

You will be given instructions to return to the physician's clinic to be examined by your doctor at one month (±15days) and 12 months (±3 months) following your surgery. These visits are standard of care and part of your routine postoperative care and follow-up. 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. 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 ventral hernia was repaired at the time of your 1-year 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 evaluate the repair, as is the standard of care. All additional procedures, interventions, and adverse events will be collected throughout the final visit at 12 months.

How long will you be in the study?

Your participation in this study will last for approximately 12 months from the date of your original ventral hernia repair surgery. You can choose to stop participating at any time without penalty or loss of routine perioperative surgical care to which you are entitled. However, if you decide to stop participating in the study, it is important you talk with your doctor first.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

Your participation in this study is completely voluntary. You do not have to take part in this study if you do not want to participate or if you 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.

The risks related to the operation are not related to your participation in this study and will be addressed with your doctor during your preoperative clinic evaluation.

4. BENEFITS

What are possible benefits of participating in the research?

If you agree to take part in this study, there is NO direct medical benefit to you. We hope the information learned from this study will benefit medical science and provide information which may help improve the field of ventral hernia surgery.

5. COSTS

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. COMPENSATION

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.

Your information will be uploaded to a national database: the Americas Hernia Society Quality Collaborative (AHSQC). This is a nationwide registry used to collect information about hernias and hernia operations and has the objective of improve the quality of care provided to hernia patients. This is a secure database and your information will not be shared in any manner that it could identify you, or with purposes not related to quality improvement or research.
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 have 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 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.

9. RESULTS

What will happen to the results of this study?

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.
If the results of this study are published, your identity will remain confidential.

10. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?

No, the researchers nor Cleveland Clinic have any conflicts of interest related to the study.

11. 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 Prabhu, MD at (216) 444-4790 during regular business hours (8am-5pm). After hours, please call the clinic operator at (216) 444-2000 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.

12. 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 a 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 Prabhu, MD at 216-444-4790 or 9500 Euclid Avenue, Cleveland, Ohio 44195.

If you choose to withdraw from the study, you will be followed based on the 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 canceled.

13. 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 signed 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 in this research study.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date