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CONSENT FORM

Prospective Randomized Controlled Trial Comparing Transvaginal Rectopexy and Ventral Mesh Rectopexy for Obstructed Defecation in Pelvic Organ Prolapse (PROD Trial)

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Sponsor: National Institutes of Health (NIH)

The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The purpose of this research is to study a newly developed diagnostic method called dynamic pelvic ultrasound. In addition, we want to compare the outcomes of two surgical procedures for the treatment of inability to completely empty your bowel and/or rectal prolapse in women: transvaginal sacrospinous rectopexy and laparoscopic abdominal ventral rectopexy. Rectopexy is a surgery where the rectum is restored to its normal position. Laparoscopic abdominal ventral rectopexy is the most common surgery used, involving mesh, where a series of small cuts are made in the abdomen. Transvaginal sacrospinous rectopexy is an innovative mesh-free procedure that is a vaginal approach to restoring the rectum position.
- **Duration.** It is expected that your participation will include undergoing the surgical procedure followed by 4 follow-up visits (2 weeks, 2-, 12-, and 24-months)
- **Procedures and Activities.** Prior to the day of your surgery, you will undergo both a dynamic pelvic ultrasound and MR defecography (explained below). You will then be randomized (like flipping a coin) to undergo one of two procedures for treatment of inability to completely empty your bowel and/or rectal prolapse: 1) laparoscopic abdominal ventral rectopexy; 2) transvaginal sacrospinous rectopexy. Following your procedure, you will be asked to return to the office for a follow-up visit 2-weeks, 2-, 12- and 24-months after your surgery. During each follow-up visit you will undergo symptom evaluation, pelvic exam and dynamic pelvic ultrasound to evaluate surgical success.

- **Risks**. Some of the foreseeable risks or discomforts of your participation include surgical risks following the procedures offered in this study. These include immediate post-operative complications as well as surgical failure.
- **Benefits**. Some of the benefits that may be expected include treatment of inability to completely empty your bowel and/or rectal prolapse using minimally invasive techniques. The follow-up offered as part of this study may enable earlier detection of surgical failure.
- **Alternatives.** You may decide you are not interested in surgical treatment of your symptoms. Furthermore, you may receive surgical treatment (either of the procedures mentioned) without enrolling in the study. Another surgical treatment option is a trans-anal rectal prolapse surgery which involves trimming of the rectum.

Detailed Information about this Study:

Introduction: You are being asked to volunteer for this clinical research study because you have presented with symptoms of inability to completely empty your bowel and/or rectal prolapse with supporting findings on an imaging test. This study is relevant if you are interested in surgical treatment for this condition.

Why is this Study Being Done?

Obstructive defecatory syndrome (ODS) is the inability to completely empty your bowel. This is a common disorder in women's health, occurring in roughly 15-20% of the adult female population. Symptoms of ODS include straining for bowel movements, feeling that you did not completely empty your bowels, and needing to use manual assistance, such as using your finger, to help pass stools. ODS is often chronic and can impact some individuals for their entire adulthood.

MR defecography is a traditional method to diagnose ODS. It uses magnetic resonance imaging to obtain images at various stages of defecation to see how well the pelvic muscles are working in bowel movements. Dynamic pelvic ultrasound is a new, less expensive, and more patient-friendly method to diagnose ODS. In the Endeavor Health Urogynecology study involving 65 participants, this method accurately predicted the presence or absence of ODS.

Laparoscopic or ventral mesh rectopexy is the most common surgery used to restore rectal support in women with ODS. It involves a series of small cuts in the abdomen and the use of mesh to hold the rectum in the correct position. Transvaginal sacrospinous rectopexy is a new, mesh-free, and vaginal route procedure that has shown promising results in treating ODS. The Endeavor Health's Urogynecology division completed a research study of this surgical procedure with 20 participants, and found the procedure to be a fairly safe and potentially effective treatment for ODS. However, it is currently unknown whether one of the surgical procedures mentioned is better than the other regarding surgical outcomes and patient experience.

We are conducting this study to explore the potential for an improved treatment outcome for women suffering from OD symptoms by:

1) Comparing two diagnostic procedures – MR defecography and dynamic pelvic ultrasound
2) Comparing the outcomes of two surgical procedures – ventral mesh rectopexy and transvaginal sacrospinous rectopexy - and considering their potential ability to improve symptoms
3) Using the anatomical imaging data to develop a new computer model to better understand what may cause OD symptoms

Recruitment for this study will occur in two participating medical centers: 1) Endeavor Health, 2) Weill Cornell Medical Center- New York Presbyterian. This study will include a total of 120 subjects. Of those subjects, 60 subjects will be from Endeavor Health.

What Will Happen During the Study?

If you agree to participate in this study, you will be asked to sign this consent form before any research-related activities are done.

Once the consent form is signed, you will first be first asked to complete the dynamic pelvic ultrasound as a part of routine clinical care. Then you will be asked to complete the MR defecography to better evaluate your rectum. MR defecography is completed for research purposes only.

You will be asked to arrive at the office with a partially full bladder. The dynamic pelvic ultrasound will be done with you lying on your back and your legs flexed 90 degrees at your hips (called lithotomy position). The first scan will be done while you are at rest. The second scan will be done while asking you to bear down (called Valsalva maneuver).

The MR defecography will be done with you lying on your back on the MRI table with hips and knees bent at 45 degrees. Four tablespoons of ultrasound gel will be applied to your rectum to make sure organs are visible for imaging. You will also be provided with headphones. Then the table will be moved into place in the MRI. During the procedure, you will be instructed via headphones to first relax and then to perform a squeeze maneuver. Then you will be instructed to perform straining and evacuation maneuvers with the goal of emptying the rectum as completely as possible.

No contrast or preparation material will be used with either of these procedures.

If you decide to proceed with surgical treatment, you will be randomly assigned to one of the two groups: 1) treatment with laparoscopic ventral rectopexy; 2) treatment with transvaginal sacrospinous rectopexy. The laparoscopic ventral rectopexy is expected to take about 30 minutes longer than the transvaginal sacrospinous rectopexy. Randomization is a procedure used to assign research subjects, by chance, to a study group in a clinical trial (similar to a toss of a coin, roll of dice, etc.). It is used to make sure study results are not influenced by the selection of subjects in one group as compared to another. In this study, you have a fifty percent chance of being assigned to one group or another. You and/or the study doctor cannot decide in which group you will be placed. Once you are assigned to a group, you cannot be switched to another group.

If you are randomly assigned to the laparoscopic ventral rectopexy group, the operation will be done through a series of small cuts in the abdomen. Mesh will be placed to prevent your organs

from falling out of place. The top end of the mesh will be tacked to the lower backbone. The lower end of the mesh will be positioned between the rectum and vagina. If you are randomly assigned to transvaginal sacrospinous rectopexy, a cut will be made in the vaginal wall. Sutures (thread-like material used to sew tissue together) will be placed to hold the rectum in the correct position. The sutures will be placed between the lateral rectal ligament and rectum, as well as between the rectum and vagina. The lateral rectal ligament is a supportive tissue in the pelvic wall, behind the rectum. Both of these operations will be performed whilst are you asleep.

Depending on pre-operational diagnostic results, pelvic organ prolapse (POP) repair procedure can be completed along with one of the two surgical procedures listed above.

For the surgical procedure, you will be treated according to the standard clinical care all urogynecology patients receive before and during such procedures, including a pre-operation pelvic exam and ultrasound.

After the surgery you will be asked to return to office for a follow-up visit 2-weeks, 2-, 12- and 24 months after your surgery. During these visits you will be asked to answer questionnaires regarding your symptoms, pain experienced after surgery, level of activity, satisfaction after your surgery and quality of life. These questionnaires may include sensitive questions and you may choose to skip any questions you do not wish to answer. You will also undergo a pelvic exam and dynamic pelvic ultrasound. Following your visit at 24-months after surgery, your participation in this study will end.

During this study, the research team will collect information about you from your medical record for the purposes of this research. This will include your age, weight, height, race, past medical history, past surgical history, information related to your surgery and data regarding follow-up visits you had after surgery.

How Long Will I Be in the Study?

You will be part of the study until your follow-up visit at 24-months after surgery. Following this visit, your participation in the study will end.

What Other Choices Do I Have?

- You may choose to treat your condition without having surgery.
- You may choose to undergo one of the mentioned surgical procedures without participating in the study.
- If eligible, you may choose to undergo a different surgical procedure, trans-anal rectal prolapse surgery which involves trimming of the rectum

Are There Benefits to Taking Part in the Study?

This study may help to determine whether one of the surgical procedures mentioned affords superior outcomes compared to the other in women with ODS. Furthermore, it may help validate the role of dynamic pelvic ultrasound in the diagnosis of ODS.

Short term: You will undergo a thorough evaluation including MR defecography and dynamic pelvic ultrasound exams. During follow up visits dynamic pelvic ultrasound will enable

assessment of rectal support achieved during surgery. You will also have the opportunity to discuss bothersome symptoms or other issues which may arise after surgery.

Long term: You will receive a thorough evaluation at 12 and 24-months during which time you will undergo a symptom evaluation, pelvic exam and dynamic pelvic ultrasound. This evaluation may reveal bothersome symptoms or compromised pelvic support after your surgery.

This study may allow doctors to learn more about how these surgical procedures work in obstructive defecation syndrome.

What Side Effects or Risks Can I Expect?

The procedures used in this study might have undesired effects. However, doctors do not know all the effects that may happen. Side effects may be mild or very serious. Sometimes they can be life-threatening. Some effects may go eventually away. The effects can be serious, long lasting or may never go away. The study doctor will watch you carefully and will provide treatment for any effects.

Questionnaires: Some of the questions asked in the questionnaires may make you feel uncomfortable. You may choose to skip any questions you do not wish to answer.

Dynamic Pelvic Ultrasound: Ultrasounds are minimally invasive, used as a part of routine urogynecology care, and conducted by trained personnel. The exam may cause transient, mild discomfort, but pose little to no immediate or long-range risk.

MR Defecography: The defecography is a painless procedure that is safe for most patients. Patients at risk for injury from MRI scans are those with pacemakers, aneurysm clips (metal clips on the wall of a large artery), or shrapnel fragments. Welders and metal workers are also at risk for injury because of possible metallic foreign bodies in the eye. You should let us know if there is any metal in your body. In the event that we determine that you have a kind of metal in your body that can interact with a strong magnetic field, you will not have a MRI.

Some subjects may experience claustrophobia or a “closed-in” feeling. You may ask the technician to stop the exam if you are unable to continue the exam.

When very high-speed methods are used for imaging, some people experience a mild twitching sensation. This should not be uncomfortable, but let us know if you experience this sensation since we can modify the imaging method to eliminate it.

The risks associated with the use of a radiofrequency (RF) coil are minimal. There is a minimal risk of skin burns if the coil is used improperly. The MR defecography staff are fully trained on the proper use of these devices.

Surgical Procedures: During this study you will undergo one of the surgical procedures mentioned. For both procedures standard risks of surgery apply including bleeding, infection and injury to nearby organs including bowel, bladder and ureters, which are the tubes that transfer urine from the kidneys to the bladder. For laparoscopic rectopexy, there are potential mesh related risk including mesh erosion and pain.
Because transvaginal sacrospinous rectopexy is a newer surgical treatment option, the frequency rate of the side effects is still unknown.

No matter which surgical procedure you receive, there is a chance that the procedure does not improve your symptoms. There is also a possibility that the doctor may decide not to proceed with the surgery once you are in the operation room. This may occur when there are unforeseeable circumstances such as encountering excessive abdominal adhesions (bands of scar-like tissue that form inside abdomen), injury to rectum during surgery, bleeding, or inability to locate surgical landmarks due to internal bodily differences.

Following your procedure, pain will be managed with appropriate medicines to achieve pain control.

Reproductive Risks: There are no known reproductive risks associated with this study.

Will My Medical Information Be Kept Private?

Information from this study could be published in journals or presented at meetings. If either of these happens, your name and other personal information will not be used. The researchers running this study will try to keep your personal information private. Your study related information may be looked at by other doctors in this study. Your research file can also be looked at by the Endeavor Health Institutional Review Board, other medical personnel at Endeavor Health who are involved in your care, or by the Food and Drug Administration (FDA).

A description of this study 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.

Will my information be used for research in the future?

Information collected from you for this research study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

Protected Health Information (PHI)

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “protected health information (PHI).” In general, under federal law, PHI is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your PHI for research and why they may need to do so.

Your PHI will only be used for the purposes described in this Consent Form. Your authorization for activities described in this section does not have an expiration date.

What protected health information (PHI) will be used?

- Past, present and future medical records, including information housed in the Electronic Medical Record called "Epic," which is maintained by Endeavor Health
- Information about research procedures, including research office visits, medical tests, procedures, interviews and questionnaires

Who may see, use and share my PHI and why may they need to do so?

- Endeavor Health research staff involved in this study
- Non-research staff within Endeavor Health who need this information to do their jobs (such as for treatment, payment (billing) or health care operations)
- The Endeavor Health IRB board that oversees the research and the Endeavor Health research quality improvement program
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US government bodies that oversee or review research)

Some people or groups who get your PHI might not have to follow the same privacy rules that we follow. We share your PHI only when we must and we ask anyone who receives it from us to protect your privacy. However, if your information is shared outside Endeavor Health, we cannot promise that it will remain private.

Do I have the right to withdraw permission for the use of my PHI?

You have the right to withdraw your permission for us to use or share your PHI for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. Once permission is withdrawn, you cannot continue to take part in this study. However, you will not be penalized or lose any benefits to which you are entitled.

Do I have access to my health information?

You have the right to see and get a copy of your PHI that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. However, to protect the study, you will not be able to see some of the study information until after the study is completed. The researchers are not required to release to you research information that is not part of your medical record.

You have the right *not* to sign this form that allows us to use and share your PHI for research; however, if you do not sign it, you cannot take part in this research study.

Will I Be Paid for Participating?

You will be paid for being in this study. For the completion of MR defecography, you will be compensated $100. For the completion of the surgery, you will be compensated $100. For each of the post-operation visits completed (2 weeks, 2-12-24 months), you will be compensated $50. In total, you can be compensated up to $400 for participating in this study.

Will There Be Additional Costs?

There is expected to be no additional cost to you from being in this research study. You will still be responsible for all costs that you would normally incur as part of routine care including costs related to the surgical treatment you will undergo. The costs that you are responsible for include the cost of the initial appointment, initial dynamic pelvic ultrasound exam, and surgery. Follow up visits, MR defecography, and ultrasound exams completed during the follow-up visits will not be billed and are free of charge.

You will still be responsible for any co-pays or deductibles as specified by your insurance plan.

What If I Am Injured During the Study?

If you become hurt or sick because of being in this research study, you can get medical treatment at Endeavor Health.

If you have a health insurance plan, your plan will be billed for the costs of treatment. If there are any costs that are not paid by your plan, you will still be responsible for any co-payments or deductibles required by your health insurance plan.

No other money has been set aside to pay any other costs you may have while in this study. You can ask for more information from the Research Institute of Endeavor Health.

Can I Withdraw from the Study?

Your participation in this research study is voluntary. If you decide not to be in this study, you can still get medical care as usual. If you decide to participate now, 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.

What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at 224/364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

Who Can I Call with Questions?

The study doctor and staff will answer any questions you have. If you have additional questions at any time during the study, you may contact the Principal Investigator, Dr. Ghazaleh Rostami Nia, at telephone: 405-326-8143.

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INDIVIDUAL PROVIDING EXPLANATION:

The procedures and/or investigations described in the above paragraphs have been explained to you by:

Name of Person Explaining Study (Please PRINT)	
Signature of Person Explaining Study	
Date Study Was Explained	

CONSENT TO PARTICIPATE:

I understand that the Principal Investigator and study staff will supervise the study. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I have been told about all of my treatment options. I give permission for the research study procedures described in this consent form.

I have reviewed this information with the study doctor and/or staff. I have had enough time to talk about all of my questions and concerns. I willingly consent to be a part of this study. I will receive a signed and dated copy of this Consent Form.

Subject's Name (Please PRINT)	
Subject's Signature	
Date Subject Signed	