The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: A prospective randomized trial comparing vaginal hysterectomy and laparoscopic supracervical hysterectomy at the time of sacrocolpopexy for the treatment of uterovaginal prolapse (Coloplast LSC HYST)
Sponsor: Coloplast
Principal Investigator: Cecile Ferrando, M.D. (216) 444-0642
Study Coordinator: Annette Graham, RN 216-445-2597
After hours phone contact #: (216) 444-2200, ask for the Gynecologist on call

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 your doctor has determined you are a good candidate for laparoscopic sacrocolpopexy (surgery to repair your uterovaginal prolapse). This happens when the uterus slips down into or protrudes out of the vagina. If you participate in the study, you will be randomized (like the flip of a coin) to either vaginal hysterectomy (removal of uterus and cervix) or laparoscopic hysterectomy (removal of the uterus only). The purpose of this study is to see if choosing a mode of hysterectomy (vaginal versus laparoscopic) at the time of sacrocolpopexy (suspension of the vagina to the ligament on the sacrum) would reduce time under anesthesia for patients. Both procedures are currently used as standard of care.

During your 6-month standard of care visit you will be asked to fill out quality of life questionnaires. Also, you will be asked to attend 2 research visits at 12 and 24-months after surgery. During your research visits you will have an examination performed and fill out quality of life questionnaires.

Your participation in the research will last about 24 months, starting from your day of surgery and ending with your 24 month postoperative visit.

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?
You might choose not to participate in this research study because you might not want to attend the research only visits.

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?
You may not receive direct benefit from being in this study. However, taking part in this study may help us to better understand how we can help manage health care for patients undergoing surgery in the future.

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

What are my other choices if I do not take part in this study?
Taking part in this study is voluntary. The alternative is not to participate.

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

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?
We would like to see if choosing a mode of hysterectomy (vaginal versus laparoscopic) at the time of sacrocolpopexy would reduce time under anesthesia for patients, and result in possible cost-savings for the hospital. Both procedures are currently used as standard of care.

How Many People Will Take Part in this Study?
Approximately 70 people will take part in this study at Cleveland Clinic.

What is involved if you decide to take part in this research study?
On the day of your surgery, you will be randomized (like the flip of a coin) to either vaginal or laparoscopic hysterectomy. Neither your doctor nor you can choose the treatment. It will be chosen by chance. In addition, we will ask you to attend two research visits at 12 and 24-months after surgery. During your research visits you will have an examination and complete a series of questionnaires. Also during your 6-month standard of care visit you will be asked to complete the same questionnaires. The questionnaires will take approximately 15-20 minutes to complete. Your participation in this study will end at your 24-month postoperative visit.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

The alternative is not to participate and to have the surgery as chosen by your surgeon. Your decision not to participate or to withdraw from the study will not impact your planned surgery.

3. RISKS

What are the risks of participating in the research study?

Confidentiality Risks

There is a potential risk of loss of confidentiality of your data; however, your information will be de-identified and anonymous. Every effort will be made to keep your information confidential. The principal investigator will do her best to protect your privacy, including your personal identity and all personal medical information, will be maintained at all times. You will be identified not by your name, but by an identification code (identification number). We will store all data with a password protected database (REDCap) with unique identifiers that will protect patient confidentiality. Only the study investigator and coordinators will have access to the data collected, which is protected for your confidentiality. This is further discussed below in the section entitled "Privacy and Confidentiality".

Questionnaire/Survey Research

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Unknown Risks

There may be risks or side effects related to the study that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

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 are no additional costs to you for participation in this research study. All costs that are part of your usual medical care (i.e. not due to participation in the study) such as costs for any procedures or visits that may be required prior to or after your surgery will be billed to you or your insurance company. You will be responsible for any co-pays or charges that are not covered by insurance. You should check with your insurance company to determine your costs before you participate in this research study.

Your 12 and 24-month research visits are not routine visits covered by your insurance and will; therefore, be paid for by the study.

6. PAYMENT

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

You will receive $200.00 following the completion of your participation. This will be paid in $50 increments following your baseline, 6-month, 12-month and 24-month postoperative visits. A parking voucher will also be provided for all visits.

The IRS requires CCF to report payments to an individual of $600 or greater (in a calendar year) on a Form 1099-MISC. Your name, address and social security number will be collected to track the payments made to you and, if you receive $600 or greater, will be used to process a Form 1099-MISC.

7. RESEARCH RELATED INJURY

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

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. 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 may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your

identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other mediums without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other mediums without your express consent.

Authorization to Use/Disclose Protected Health Information

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.

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 include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor (Coloplast Corporation) of the research and their agents. 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, Cecile Ferrando, M.D., 9500 Euclid Avenue/A81, 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 Language

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 or concerns about the research, or develop a research-related problem, you should contact Cecile Ferrando, M.D at 216-444-0642. After business hours, you may contact the Gynecologist on call by calling the Cleveland Clinic page operator 214-444-2200. If you have questions about your rights as a research subject, you should contact the 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.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

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

If needed for remote consenting:

_____

Printed name of Witness (Remote Consenting)

_____ _____

Signature of Witness (Remote Consenting) Date