MedStar Health

Permission to Take Part in a Human Research Study

Title of research study: **Assessment of Tubal Occlusion During Minimally Invasive Myomectomy**

Investigator: Alexis Dieter, MD**and Alexandra Snyder, MD**

Sponsor/Funding Source or Support: **Department of Graduate Medical Education – MedStar Health/Georgetown University**

Disclosures: Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are **undergoing robotic or laparoscopic surgery for fibroids with a surgeon in the Department of Minimally Invasive Gynecologic Surgery** at **a MedStar** hospital.

What should I know about a research study?

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

Why is this research being done?

This study is being done to better evaluate the health of the fallopian tubes in patients with fibroids. The fallopian tubes are essential for achieving pregnancy without the help of fertility interventions like IVF. Few studies have been done to assess how fibroids affect the function of fallopian tubes. The purpose of this study is to help us better understand the effects that fibroids and fibroid surgery have on fallopian tube blockage, and to determine if there is a difference in how open (or "patent") the fallopian tubes are before performing surgery and immediately after surgery is complete. This study will take a technique called chromopertubation that is used for infertility evaluation and apply it to patients who have fibroids.

We hope that understanding more about how these fibroids affect fallopian tube function will help us better understand, diagnose, and treat fallopian tube disease that may lead to infertility.

How long will the research last and what will I need to do?

We expect that you will be in this research study for the duration of your surgery.

You will not need to undertake any additional tasks to participate in this study. All of the study will be performed during your surgery while you are asleep. This study will not have any effect on the planned surgery to remove your fibroids (myomectomy). Your surgeon will use a solution of blue dye inserted into the uterine cavity at the beginning and end of the surgery to check if the fallopian tubes are open. This is a procedure that is commonly performed for patients being evaluated for infertility.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be part of this research?"***

Is there any way being in this study could be bad for me?

Most of the risks associated with the procedures in this study are the risks of undergoing laparoscopic surgery. There is a very small (<1%) risk of an allergic reaction to the dye used to evaluate the fallopian tubes. This reaction is rare and can include mild symptoms such as itching, rash, shortness of breath, nausea, headache or dizziness. More serious reactions such as pulmonary edema (fluid in the lungs) or anaphylaxis are very rare. This procedure uses a very low dose of dye in order to further minimize the potential for these reactions. The materials and procedure described in this study are well-established and commonly performed in infertility evaluation.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

Patients who take part in this study will receive the gold-standard (considered the best) procedure for assessing the fallopian tubes and will get information about the current function of their fallopian tubes.

However, this purpose of this study is to see how the tubes function before and immediately after surgery, so this information does not necessarily represent the function of your fallopian tubes or chances of fertility in the future. This study and procedure are not intended to diagnose or treat infertility.

Therefore, you may or may not get any direct benefit from being in this study. We hope the information learned from this study will benefit others in the future.

What happens if I do not want to be part of this research?

Participation in research is completely voluntary. You can decide to participate or not to participate.

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

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can contact **Dr. Alexandra Snyder at the National Center for Advanced Pelvic Surgery at 202-877-6526.**

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (301) 560-2912 or MHRI-ORIHelpDesk@medstar.net if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

For questions about your rights as a research participant, contact the MedStar Health Research Institute. Direct your questions to the Office of Research Integrity at:

MedStar Health Research Institute
10980 Grantchester Way, 7th Floor,
Columbia, MD 21044
301-821-1530

How many people will be studied?

We expect a minimum of 50 people will be in this research study.

What happens if I say yes, I want to be in this research?

- Background information about your health and past medical procedures will be collected by the research team from the information in your chart. This will be kept confidential.

- During this study, a procedure known as chromopertubation will be performed in the operating room at the beginning of the surgery before starting the myomectomy (fibroid removal) and again at the end once the surgery is complete. This procedure includes injecting a solution of dilute medical-grade blue dye into the uterus to look for spillage of the dye solution out of the fallopian tubes. This shows whether the tubes are open or blocked.

- Chromopertubation is a safe, commonly used and well-established medical procedure that is done for patients experiencing infertility, endometriosis, or are otherwise concerned about the health of their fallopian tubes. It is considered to be the best way to evaluate whether or not the fallopian tubes are blocked. It is important to remember that while this is the best available test, it is still not 100% accurate. If the tubes are not confirmed to be open during this procedure, that does not automatically diagnose infertility. This test does not guarantee that the fallopian tubes will remain blocked or open in the future. If there are concerns about tubal blockage, future testing may be recommended by your surgeon.

- This study does not include any new medical procedures or medications. The experimental portion of this study is how, when, and for whom we are using this procedure in order to gather new information. Specifically, performing chromopertubation for patients with fibroids both before and at completion of surgery and recording this information to better understand how fibroids and fibroid surgery affect the fallopian tubes.

What happens if I say yes, but I change my mind later?

You can leave the research at any time it will not be held against you.

If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data.

Is there any way being in this study could be bad for me? (Detailed Risks)

As noted, the procedure in this study is routinely performed for other indications such as fertility, endometriosis, and pelvic infections. It is considered a safe an established medical procedure. Complications resulting from the procedure are rare and may include an allergic reaction to the dye that is used.

The procedures in this research are known to hurt a pregnancy or fetus by causing loss of the pregnancy. You will not be able to participate in this study if you are discovered to be pregnant on the day of surgery.

Taking part in this research study may lead to added costs to you in the rare event that you have an adverse reaction to the materials used in the study. You and your insurance company will be charged for the health care services that you would ordinarily have to pay for and any costs associated with providing you necessary medical care.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. This includes members of the research team. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information that is collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

HIPAA Authorization

We are committed to respecting your privacy and to keeping your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information including the health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. The health information we may collect from you and use for this research includes:

- Information in your medical records necessary for this research
- Results of physical examinations
- Medical history
- Radiology imaging

- Lab tests, or certain health information indicating or relating to a particular condition as well as diaries and questionnaires
- Records about study medication or drugs

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of MedStar Health and its clinical partners (or affiliates): the MedStar Health Research Institute Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or MedStar Health policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the MedStar Health workforce, who may need to see your information, such as administrative staff members from the MedStar Health Research Institute, Office for Research Integrity and members of the Institutional Review Board.

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those people may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

This research authorization will remain in effect until the end of the study unless you revoke consent for participation in this study. If you revoke consent MedStar Health may not gather new information about you or use or disclose your personal health information collected in this study for any purpose other than the research study described in this consent unless MedStar Health obtains permission to do so from you.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Alexis Dieter, MD
Institution: MedStar Health National Center for Advanced Pelvic Surgery
Address:
106 Irving Street NW
Physicians Office Building
South Tower Ste. 405
Washington, DC 20010

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study if you do not allow this. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Can I be removed from the research without my consent?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include inability to proceed with the planned fibroid surgery, an adverse reaction to the methylene blue dye solution, a positive pregnancy test on the day of surgery, or other complications related to the surgery that prevent us from performing the study interventions for your own wellbeing.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research study.

What else do I need to know?

If you need medical care because of taking part in this research study, contact the investigator and medical care will be made available. Generally, this care will be billed to you, your insurance, or other third party. MedStar Health has no program to pay for medical care for a research-related injury.

If you feel that you are having a medical emergency, you should go to the emergency room right away.

The tests performed in this study are intended only for research and have no clear meaning for health care. It is not known if the results will have meaning for your health. The research performed in this study is not "blinded," and you can ask to be informed of the results at any time.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	