Permission to Take Part in a Human Research Study

Title of Research Study: The effect of decreased uterine filling pressure in hysteroscopy, a double-blind randomized control trial

Investigator: Dr. Magdy Milad

Supported By: This research is supported by Northwestern University Department of Obstetrics and Gynecology

If your doctor is also the person responsible for this research study, please note that s/he 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 first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are scheduled to undergo an operative or diagnostic hysteroscopy procedure for management of polyps and or fibroids as part of standard of care.

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 research is being done in order to maximize the comfort for patients undergoing hysteroscopic procedures. During these procedures, saline is used to expand the uterus so the surgeon can see within it. Currently, the pressure used for this is 80 mm Hg. This study will determine if lowering the pressure to 60 mm Hg is effective for the surgeon and also eliminates the need for patients to receive Lasix after their surgery.

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

You will be in this research study only during the time of your procedure.

Permission to Take Part in a Human Research Study

You will show up to your scheduled procedure as you normally would. The study procedure will take place during your scheduled surgery, while you are in the operating room. Participation will add less than one minute to your procedure and will not change the planned procedure.

More detailed information about the study procedures can be found under the section What happens if I say "Yes, I want to be in this research"?

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

During the procedure, monitoring will be done by anesthesia through the use of pulse oximetry and measurement of vitals during the Monitored Anesthesia Care, which is standard of care for the hysteroscopy procedure.The only change that may occur from being in the study is a lower pressure of saline used to visualize the uterus. If the surgeon believes they cannot see well enough at any point during the procedure, they can ask for the pressure to be increased to ensure appropriate visualization. For this reason, there is no additional risk to you by participating in this study.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

Will being in this study help me any way?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include a decreased need for diuretics after your procedure.

What happens if I do not want to be in this research?
Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. Dr. Magdy Milad is the person in charge of this research study. You can contact him or study personnel at 312-472-4673 during business hours and via

a pager system after hours by calling 312-694-6447. You can also contact the study coordinator, Jeremy Cornelius at jeremy.cornelius@nm.org with any questions.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu 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.

How many people will be studied?
We expect about 68 people will be in this research study.

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

- If you consent to participate, you will be sign this consent form during your preoperative appointment and receive a copy of it including the study coordinators signature
- You will arrive at your schedulued surgery date and time as you would normally
- You will undergo your scheduled procedure with either the standard or experimental pressurization using a MyoSure device. Standard pressurization during hysteroscopy at Northwestern Medicine is 80 mmHg, and this will be reduced to 60 mmHg in the experimental pressurization, depending on which randomized group you are in.
- You will be randomly sorted into one of the two groups of either 60 or 80 mmHg in pressurization, and this randomization process is like flipping a coin to determine which of the two groups you will be sorted into.
- You will be discharged as you normally would be upon completion of your procedure

The pressurization you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what pressurization you get. You will have a one in two chance of being given either treatment.

Neither you nor the study doctor will know which pressurization you are getting.

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.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not

to be in this study will not negatively affect your right to any present or future medical treatment.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any costs to you.

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. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

What else do I need to know?

You will receive no compensation for participating in this research study.

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

HIPAA Authorization
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes 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. Your health information we may collect and use for this research includes:

- Medical history

Permission to Take Part in a Human Research Study

During this study, you may be coming to a Northwestern Memorial Healthcare Corporation entity (for example, Northwestern Memorial Hospital, Prentice Women's Hospital) for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH).

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and 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 University 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 Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), Northwestern Lake Forest Hospital (NLFH), and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH), and Northwestern Lake Forest Hospital (NLFH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Study monitors and auditors who make sure that the study is being done properly,

Permission to Take Part in a Human Research Study

- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

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 persons 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.

Unless you revoke your consent, it will not expire.

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: Magdy Milad, MD
Institution: Northwestern University, Northwestern Medicine
Department: Obstetrics and Gynecology – Division of Minimally Invasive Gynecologic Surgery
Address: 259 E. Erie, Suite 2450, Chicago, IL 60611

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 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.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____

Permission to Take Part in a Human Research Study

Printed Name of Person Obtaining Consent