Online Consent to Participate in Research

Title of Research Study: *STU00091259*
*Buccal Misoprostol Prior to Myomectomy for Reduction in Intraoperative Blood Loss: A Placebo Controlled Randomized Trial (*NCT02209545)

Investigator: Magdy Milad, MD

Supported By: This research is supported by the Gerbie Professorship

Financial Interest Disclosure: The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

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.

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 undergoing surgery to remove fibroids.

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.

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?
The purpose of this study is to evaluate the use of a medication, misoprostol, for reducing blood loss during fibroid removal (myomectomy). You are being asked to participate because you are undergoing a surgery to remove fibroid/s from your uterus. Research suggests that a commonly used medication, misoprostol, may reduce blood loss during fibroid surgery. We are performing this research study to evaluate whether blood loss is reduced when patients receive misoprostol before surgery. The use of misoprostol in this context is considered experimental.

How long will the research last and what will I need to do?
We expect that you will be in this research study at the time of your surgery both pre and post operatively. You will need to attend all normal preoperative and postoperative visits that you would normally attend for this type of fibroid surgery.

Is there any way being in this study could be bad for me?
The risks from the study procedures include the risk of discomfort from being asked to place a medication between your cheek and gums for 30 minutes then swallow.

Will being in this study help me any way?
There may be no benefit to you from this study. The possible benefits to you from this study include less blood loss during your fibroid surgery Taking part in this study may help scientists to better how to reduce blood loss during fibroid surgery. Your participation may one day benefit other women, allow them to recover from surgery more quickly or even save their life.
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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.

You do not have to take part in this research study. Instead of being this study, you can undergo fibroid surgery without premedication. Speak with your doctor about your concerns or desires

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

Who can I talk to?
You can call us with your questions or concerns. If you have any illness or injury during your time on this study, you should call us promptly. Dr. Magdy Milad, M.D. 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 312-695-7269 regarding this study.

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 70 people here 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 required to have an office visit within 90 days of your surgery where a review of your medical history and medications, a physical exam and laboratory blood tests including a measure of your blood count (hemoglobin) will be taken. This visit will be with your surgeon and not outside of what he/she would require prior to surgery regardless of your participation in this study. You will then be randomized to a treatment group (misoprostol or placebo (vitamin B6)) and will be provided a buccal (between gum and cheek)

medication to take 1 hour before your surgery. You will have a pregnancy test as part of your preoperative evaluation.
After surgery, researchers will take note of information like the amount of blood loss and your lab test results after surgery (at least 4 hours postoperatively), but no further participation is required on your part. You will receive the standard-of-care fibroid surgery regardless of your treatment arm or participation in this study.

Randomization
Randomization means you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group (placebo (vitamin B6) or misoprostol).

Placebo
This study compares an active drug to a placebo. A placebo is an inactive substance made to look/taste like an active medicine. In this study, the placebo drug is a one-time dose of vitamin B6. B6 is a vitamin that is commonly taken as a supplement.You will either get the study drug, misoprostol or a placebo (vitamin B6). Researchers use a placebo to see if the study drug works better or is safer than not taking anything.

Misoprostol
Misoprostol is a commonly used medication that is prescribed for the prevention of gastric ulcers and controlling post-partum hemorrhage (life-threatening uterine bleeding after a vaginal or cesarean delivery). A low-dose of misoprostol will be used in this study.

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

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

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible to attend all necessary preoperative and postoperative appointment with your surgeon. These appointements are the same as they would be for any patient undergoing a similar surgery.

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 decide to leave the research, contact the investigator so that the investigator can withdraw you from the study.

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.

Detailed Risks:
Risks from Placebo
Vitamin B6 is given for nutritional deficiencies and is considered a safe drug. Side effects can include headache, nausea and, in large doses, neuropathy (weakness, numbness and pain, usually in your hands and feet).

Risks of Misoprostol
The risks associated with misoprostol include: abdominal pain (7%), nausea (3%), flatulence (gas) (3%), headache (2%), indigestion (2%), (7%), vomiting (1%), constipation (1%). Research studies also identify possible side effects of diarrhea, fever and shivering. There may also be other side effects that we cannot predict, of either the placebo drug or misoprostol. Should you experience significant discomfort whether physical, psychological or otherwise, you may opt out of the study at any time.

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?".

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The procedures in this research are known to harm a pregnancy or fetus in the following ways: It may cause miscarriage, premature labor, or other complications.

You should not be or become pregnant while on this research study.

If you are sexually active, women should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or your partner [are/is] considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal women rarely become pregnant. If you or your partner become pregnant while participating in this research study or for 12 months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

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.
If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted

direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Can I be removed from the research without my OK?
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 complete your surgery, and inability to obtain complete follow-up data.

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

What else do I need to know?
If you become ill or get 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 [university, researchers] 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:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Billing information

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].

- 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,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).
- Registries or other research-related databases: RedCap

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.

However, Illinois law does not allow the re-release of HIV/AIDS, genetic testing, mental health and developmental disabilities information by the recievers of the information except in precise situations allowed by law.

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: Magdy Milad, M.D. Northwestern University, Northwestern Memorial Hospital Center for Comprehensive Gynecology 259 E. Erie Street- 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.

Consent

If you want a copy of this consent for your records, you can print it from the screen.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

If you wish to participate, please click the "I Agree" button and you will be taken to the survey.

If you do not wish to participate in this study, please select "I Disagree" or select X in the corner of your browser.]