Permission to Take Part in a Human Research Study

Title of Research Study: Surgeon Perception of Gastric Decompression at time of Gynecologic Laparoscopy, a Randomized Control Trial (STU00219580)

Principal Investigator: Magdy Milad, MD

Supported By:
This research is supported by the Center for Complex Gynecology at Northwestern University.

Disclosure: If your doctor is also the person responsible for this research study, please note that ***they are*** 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 undergoing a gynecologic laparoscopic procedure.

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?
Commonly during gynecologic laparoscopic surgeries, a tube is placed via the nose (nasogastric) or mouth (orogastric) to decompress and empty the stomach during surgery. Data is limited on the benefits of this practice for these types of surgeries specifically. Additionally, there are risks associated with the use of a nasogastric or orogastric tube. We are evaluating the routine use of nasogastric or orogastric tube placement during gynecologic laparoscopic surgery to determine whether it is necessary or beneficial.
Currently available anesthesia guidelines recommend the routine use of tube placement during surgery. Theoretically, placement of the tube empties the stomach during surgery, decreases the risk of stomach injury, improves visualization, and decreases postoperative nausea and vomiting. However, research shows that tube placement does not actually guarantee full

emptying of the stomach or decrease rates of nausea. There is some data to suggest that tube placement decreases the possible risk of stomach injury during surgery, but overall this is an incredibly rare complication, occurring less than 0.5% of the time. Furthermore, there have been documented risks of tube placement including higher rates of fever, lung complications, and more patient discomfort.
This study is important as there are no studies to date which have investigated the utilization of intraoperative tube placement specifically for gynecologic laparoscopy. The potential benefits of avoiding unnecessary tube placement include decreased risk of lung infection, less discomfort to the nose, mouth and throat, decreased risk of fever, and faster return to normal bowel function following surgery. The results of this study may also improve the experience of gynecologic laparoscopy for future patients.

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

We expect that you will be in this research study until six weeks after your surgery.

You will be asked to present and undergo your surgery and allow us to review your medical chart for any encounters that occur up until six weeks post-operatively. With your permission, we may contact you in the post-operative period after you leave the hospital to ask you about your recovery. We also ask that you complete a postoperative recovery symptom diary for the first two weeks after surgery. You can bring this log to your post operative appointment or send directly to the research team.

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?

The risks of participating are minimal. If you choose to participate and are selected for the experimental group (no tube placement), you may experience increased nausea and vomiting after surgery which can be managed with standard medications. It is possible that the risk of injury to the stomach during surgery is higher if a tube is not placed. However, this has not been studied. Additionally, if the type of surgery you are having has a high risk for stomach injury, if you have preexisting conditions which make you high risk, or if your surgeon or anesthesiologist ever (including during surgery) think it would be safer for you to undergo tube placement, you will ineligible to participate in the study.

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 anyway?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include decreased risk of lung infection or fever, less discomfort to the nose, mouth or throat, and faster return to normal bowel function. It is possible that this study could benefit other patients who undergo gynecologic laparoscopy in the future.

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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.

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 at 312-694-6447.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irbcompliance@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 150 people will complete this research study at Northwestern Memorial Hospital.

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

If you agree to participate, 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.

On the day of surgery, all of the preoperative preparations will follow usual protocols. If you are in the standard of care group, after you are asleep from anesthesia, the Anesthesiologist will place a nasogastric or orogastric tube. Your surgery will proceed as usual. At the beginning of the surgery, your surgeon will answer three short questions which describe their impression of visualization during surgery. The tube will be removed before you wake up from anesthesia. If you are in the experimental group, after you are asleep from anesthesia, the Anesthesiologist will refrain from placing a nasogastric or orogastric tube. Neither you nor the study doctor will know which study group you are in. After surgery, the usual postoperative care will be initiated. For the first two weeks after your surgery, we would like you to keep a daily log of common postoperative symptoms and milestones. Each day, we would like you to record if you have nausea, vomiting, and nose or throat discomfort. We would also like you to document which

days after surgery you pass gas and have a bowel movement. When you return for your postoperative visit, you should bring the log to your appointment to give to your surgeon. This log should take less than a minute to complete each day.
At any time you can choose to withdraw yourself from the study before completion.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for: following all of your preoperative instructions, arriving on the day of surgery, undergoing surgery, and completing a daily log of postoperative symptoms and milestones for two weeks after your 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 the investigator can communicate to the surgical team and anesthesia team that you have withdrawn from the research 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.

If you agree, this data will be handled the same as research data. We will use the data collected up until the point of withdrawal.

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

Regardless of participation in the research, the risks of undergoing surgery include bleeding, infection, damage to surrounding structures including the risk of stomach injury, need for additional procedures in the future, need for blood transfusion, and need for laparotomy, which is a large incision or cut, often made up and down the abdomen through the skin and abdominal wall tissue, to see inside the belly.
If you are selected to be in the experimental group who does not undergo tube placement, this research may hurt you in the following ways:

- Postoperative vomiting
- A theoretical increased risk of stomach injury (an unintentional hole created in the stomach), though this has not been studied.
    - If the stomach is injured it would need to be repaired with stitches by a specialist and there may be diet restrictions during the healing period.
- The potential that surgeons will have decreased visibility during surgery, though this has not been studied. Additionally, if it impacts the ability of your surgeon to safely perform your surgery, they will ask for tube placement.

In addition to these risks, this research may hurt you in ways that are unknown.

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?".**

There are no anticipated legal, social, economic, or community risks.

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

If you become pregnant while participating in this research study or for two weeks 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.

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. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research.

However, possible benefits if you are in the experimental group (no tube placement) include:

- Lower risk of lung infection or fever
- Less discomfort to the nose, mouth or throat
- Faster return to normal bowel function

By participating in this project, it is possible that other patients who undergo gynecologic laparoscopy in the future may benefit.

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 Northwestern, US Department of Defense Health and Human Services, and IRB.

The data collected from this study will be retained for three years.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity (ORI), the US Office for Human Research Protections (OHRP), and 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.

A description of this clinical trial 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.

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. 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 difficulty with intubation, vomiting on the day of surgery, concern about the need for surgery on your intestines (i.e. bowel), or the need to make an incision in the upper part of your abdomen during surgery.

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?

You will not be paid for your participation in this 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 [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 devices
- Billing information

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During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity 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) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

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; and 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 Northwestern Memorial HealthCare, 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.
- Other University research centers and University contractors who are also working on the study,
- 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).

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.

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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 expire at the end of the research study.

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.

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

_____
Printed Name of Person Obtaining Consent