Northwell Health

Campus: North Shore, Long Island Jewish, Lenox Hill, South Shore, Huntington Hospital, Peconic, Mather, Plainview

Consent for Participation in a Research Study

Study Title: Clinical effectiveness of pre-incision versus post-incision local anesthetic during laparoscopic/robotic sacrocolpopexy

Principal Investigator: Harvey Winkler, MD

About this research
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Important Information
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why am I being asked to provide my consent?	This is a research study, which is different from personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
Do I have to join this research study?	No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled.
Why is this research study being done?	Our study aim is to find out if there is a certain timing during surgery of injecting Marcaine (a local numbing medicine) into the incision sites that would help decrease pain and decrease narcotic usage after a robotic/laparoscopic sacrocolpopexy (the abdominal surgery which uses a camera and the use of very small surgical tools that are attached to robotic arms to lift the vaginal walls and/or cervix), the procedure that you will be getting.
What will happen to me during the study?	Although injecting the local numbing medicine into incision sites is standard of care during the procedure which you will be getting, if you agree to participate in this study, you will be randomly assigned to either getting the local numbing medicine before the incision (for the surgical tool placement) or gets the local numbing medicine at the end of the procedure, and there is an equal chance of being in either group. You will also be asked to complete a questionnaire about your pain prior to

	surgery and after surgery in addition to keeping a diary about pain medication that you take during the 2-week period after your procedure.
How long will I participate?	The study participation is for a total of two weeks.
Will taking part expose me to risks?	Since you will be randomly assigned to one of the groups, your group may receive less effective treatment or have more side effects than the other group. In addition, this research will collect your personal health information. There is a risk of breach of confidentiality, and every effort will be made to protect the confidentiality of your data.
Are there any benefits to participation?	The research may or may not benefit you directly. Depending on which group you are assigned to, you may have decreased pain after surgery.
What are my alternatives to participation?	Marcaine (the local numbing medication) is still available to you without joining the study because this medication is currently being used in standard of care practice, but the timing of the injection will be decided by your doctor.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Introduction
You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Financial Disclosure: *There are no financial disclosures.*

Why is this research study being done?
The purpose of this research study is to figure out if there is an optimal timing to the current standard of practice of applying local numbing medication during a procedure to decrease pain for patients. Ultimately, our aim is to evaluate if there is a way to decrease opioid pain medication use for patients.

Why is this research?
This is a research study because currently injecting Marcaine (a local numbing medicine) to incisions is the current standard of care during the surgery. However, as of right now, there is no

known optimal timing to inject Marcaine. Our aim is to find out if there are changes in pain levels if the Marcaine is injected before making the incisions or after making the incisions.

Marcaine has already been approved by the Food and Drug Administration (FDA) as a local numbing medicine for surgery. The researchers are interested in finding out the optimal timing to inject Marcaine for reducing pain after surgery.

You are being asked to participate in this study because you are undergoing the prolapse repair that includes the robotic-assisted laparoscopic sacrocolpopexy.

How many people will take part in this study?
This research study hopes to enroll 128 participants.

How long will you be in this study?
If you choose to take part in this study, you will be in this study for two weeks. You will not be followed for any longer than the two weeks and you will not be asked to attend any additional visits for the study aside from your routine postoperative care.

What will happen in this research study?
In this study you will be randomized. This means that you will be assigned to a group by chance (like flipping a coin). You will have an equal chance of being in either (or any) group. The study is done this way because knowing whether you are in a group can change the results of the study. The research study staff will know which group you are in, but we will not tell you which group you are in so that the study data will be not be biased.

If you agree to participate, as part of this research study, you will be asked to complete a questionnaire about your pain one time before surgery and one time after surgery at your standard 2 week postoperative visit. You will also be given a narcotic diary at that same time for you to hold on to until after your surgery. On the day of surgery, you will be randomized into one of two groups: you will either be getting the incision site injection of Marcaine before incision is made, or you will be getting the injection of Marcaine after the incision is made. About 18-24 hours after your surgery, you will be asked about your pain and given a diagram to view to assess how much your own pain is currently. If you are in the hospital, you will be asked this question in the hospital by one of the providers taking care of you. If you are home, you will be called to inquire about your pain. There are no changes in postoperative restrictions or dietary restrictions. At the time of discharge, you will be given pain medications as part of your routine clinical care. At your first postoperative visit which is about two weeks after surgery, you will be asked to provide your completed narcotic diary in which there is written how many tablets of oxycodone you took each day and you will be given the same questionnaire that you received prior at the time of consenting to fill out again. This will be the end of the study.

Drugs and Devices

- The medication we will be using is 0.25% Marcaine (generic name: Bupivacaine) The route of administration: right underneath your skin at the incision sites
- The medication route is FDA approved

What are the risks of the research study? What could go wrong?
Since you are being randomized, your group may receive less effective treatment and/or have more side effects than the other group.

This research will collect your personal health information. There is a risk of breach of confidentiality, and every effort will be made to protect the confidentiality of your data.

Collection of Sensitive Information
Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study.

Unknown Side Effects
As with any drug, there might be side effects that are unknown at this time. You will be closely watched for side effects. You should report any unusual events to the study staff.

The medication that is currently being used on you is the current standard of practice, so you may experience the following risks even if you are not in this study:

- The most common risks that could take place with the study medication includes swelling and bruising of the incision site.
- In rare situations, if the medication is given in large doses, it can cause abrupt loss of heart function which could lead to death.
- It can also lead to a blood issue in which the blood is unable to carry oxygen (the air in which we breathe).
- Because we are injecting your skin with medication, then it may cause you to bleed at that site momentarily or you may experience numbness at that site for several hours.
- Other risks include severe allergic reaction and low blood pressure.

What are the benefits of this research study?
This research may or may not benefit you directly. Your group might receive more effective treatment and/or have fewer side effects than the other treatment group. Depending on which group you are in, you may have decreased pain and not require as much pain medication when you are at home.

In addition, information we learn about this may help patients in the future.

If you do not want to take part in this clinical research study, what are your other choices?
If you do not join this study, Marcaine (the local numbing medication) is still available because it is being used in standard of care, but the timing of the injection will be determined by your doctor.

Are there any costs for being in this research study?
The study medication is the current standard of practice involved in your surgery. The medication and all other costs will be billed to you or your insurance company in the usual way, as part of your standard care.

Will you receive any payments for participating in this research study?
You will not receive any payments for participating in this research study.

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data (or samples) already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies such as the Food and Drug Administration (FDA).
- Representatives from Northwell Health's Human Research Protection Program (the group of people that oversee research at this institution)

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Dr. Harvey Winkler
865 Northern Boulevard
Great Neck, New York 11021

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we

cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
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 website at any time.

Will my information be used for research in the future?
Information for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified data to be used by future researchers without additional consent.

Does the investigator of this study receive money if you take part?
The investigators on this study do not receive money for your participation in this study.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Vini Chopra at 646-655-8533. If you have questions about side effects or injury caused by research you should call Dr. Harvey Winkler at 516-622-5114. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, or concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465-1910. A signed copy of this consent form will be given to you.

Summation/Signature
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Witness Date

_____
Printed Name of Witness
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name