Cover Page for ClinicalTrials.gov

Document: Informed Consent

Official Study Title: Cyclobenzaprine for Postoperative Pain in Minimally Invasive Hysterectomy: A Randomized Controlled Trial

Document Date: 04/10/2026

INFORMED CONSENT

Title of Study: Cyclobenzaprine for Postoperative Pain in Minimally Invasive Hysterectomy: A Randomized Controlled Trial

Principal Investigators: Margaret Wingo, MD and Kathryn Denny, MD

Sub-Investigators: Michelle Pacis, MD; Monique Farrow, MD; Richard Hsu, MD; Kristyn Mitchell, MD; Nakia Wighton, MD, Kathryn Bankhart

Department: Obstetrics and Gynecology, subspecialty Minimally Invasive Gynecologic Surgery

Contact Phone Number: 302-623-4410

Sponsor: ChristianaCare Health Services

INTRODUCTION
You have been asked to take part in a clinical research study. For the purposes of this informed consent, the use of the word "you" refers to either yourself or a legally authorized representative. Before you agree to join this study, you need to know the risks and benefits so you can make an informed decision. This consent form describes the purpose, procedures, possible benefits, and risks of the study.

Your study doctor will discuss the clinical research study with you. Clinical research studies include only people who choose to take part. Please take your time to make your decision. Discuss it with your family, friends, and health care team. Please read this document carefully and if you have any questions, you can ask your study doctor for further explanation.

You are being asked to take part in this study because you are planning to undergo a hysterectomy using a minimally invasive approach (i.e. laparoscopic or robotic).

The person responsible for this study at ChristianaCare is Margaret Wingo, MD. She is available in the department of Obstetrics and Gynecology by phone at 302-623-4410. Neither Dr. Wingo nor ChristianaCare receives reimbursement for the costs of conducting this study.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to gather more information on cyclobenzaprine as part of postoperative pain control. Cyclobenzaprine, aka Flexeril®, is NOT an experimental drug and is already approved by the Food and Drug Administration (FDA) for acute, painful muscle spasms. It is commonly used for muscle-related pain disorders.

This research is being done because prior studies have shown that cyclobenzaprine helps with pain due to muscle spasms. Some studies showed that cyclobenzaprine does help reduce pain scores in patients undergoing abdominal or joint surgery, but the studies are very limited. This

study will see if cyclobenzaprine can be used to decrease post-operative pain in patients undergoing minimally invasive hysterectomy.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
About 36 people will take part in this study from women undergoing a minimally invasive hysterectomy within ChristianaCare.

WHAT IS INVOLVED IN THE STUDY?
You will be "randomized" into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. Which group you are put in is done by a computer. *Both you and the researcher will know what group you will be in*. You will have an equal chance of being placed in one of the two groups.

By participating in this study, you may have a change in your clinical care from your surgical team. The actual operation will not change at all. You will be given the same pre and post operative medications as you would normally receive if you do not participate in this study. You will be requested to complete a short survey electronically at 1, 3, and 7 days postoperatively. Per normal nursing protocols, you will also be asked in person to rate your pain prior to being discharged from the hospital.

If you take part in this study, you will have the following tests and procedures:
You will continue to have your routine care by your surgical team; this includes being met on the day of surgery in the preoperative prep and hold area. You will be given preoperative medications including pain medication as is the routine at ChristianaCare. You will have no changes to your scheduled procedure/surgery. You will continue to receive the standard of care for your postoperative care in regards to monitoring, laboratories, and discharge care. You will continue to receive routine postoperative pain medications.

However, by participating in this study, you agree to be randomized to either receiving or not receiving cyclobenzaprine. Those who receive cyclobenzaprine will get a week's worth of medication post-operatively. You also agree to have personal health information collected about you from your medical records including details regarding your surgery and your baseline health including your weight, past medical and past surgical history. More information on how we will protect your PHI can be found under the section titled 'What about Confidentiality?' on page 4.

HOW LONG WILL I BE IN THE STUDY?
You will be a part of the study for one week.

CAN I STOP BEING IN THE STUDY?
You can stop being in the study at any time.

WHAT ARE THE RISKS OF THE STUDY?
While on the study, you are at risk for some side effects. The study doctor will discuss these with you. There also may be other side effects that we cannot predict. Side effects may be mild or very serious. Other drugs or treatment may be given to make side effects less serious and uncomfortable. Many side effects go away shortly after the medication is stopped, but in some

cases side effects can be serious or long lasting or permanent. If side effects become severe, hospitalization may be necessary for treatment. Although rare, death is possible.

Risks and side effects related to cyclobenzaprine include:

More likely (greater than 3%)

- Dry mouth
- Drowsiness or sleepiness
- Fatigue or lack of energy
- Headache

Less Likely (between 1-3%)

- Dizziness
- Irritability or nervousness
- Abdominal pain
- Heartburn
- Constipation or diarrhea
- Nausea
- Dilated pupils or blurry vision

Very Unlikely

- Allergic reaction (can be mild or severe ranging from severe itching, hives/rash, difficulty breathing, life-threatening full body reaction called anaphylaxis)
- Fainting
- Fast or irregular heartbeat
- Inability to empty your bladder
- Neurologic effects such as imbalance, confusion, trouble sleeping, hallucinations, or seizures
- Dependence or risk of abuse

You should not take cyclobenzaprine if you have an irregular heartbeat or heart block, recent heart attack, heart failure, or hyperthyroidism. Participants are asked to abstain from any alcohol and recreational drug use. The study investigators will review your medication list to determine your eligibility to be in the study, and will exclude you from participating if you take any medications that could interact with cyclobenzaprine or lead to increased sedation.

There is a *theoretical* risk of developing serotonin syndrome,a potentially serious reaction, when taking cyclobenzaprine together with other kinds of medication affecting how your body makes/uses serotonin, such as antidepressants. Serotonin syndrome happens when there is too much of a brain chemical called serotonin in your body. This can cause symptoms such as feeling shaky, sweaty, slightly confused, or having a fast heartbeat. Most cases are mild and go away after stopping the medication. Published data shows that the amount of medication needed to get serotonin syndrome is much more than what will be prescribed in this study, even if you take other medicines affecting serotonin.

There is a *potential* risk of increased sedation by taking cyclobenzaprine and oxycodone simultaneously. This risk is minimized by taking oxycodone only as needed, and both medications are only prescribed for short courses.

Risks of completing a questionnaire/survey: Some people may feel some anxiety while completing a survey due to the nature of the questions asked. You may skip any questions that bother you. If you do not answer some or all of the questions, it will not affect your taking part in the study.

For more information about risks and side effects, ask the study doctor Margaret Wingo, MD.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, it is possible that you may not benefit. The study drug (cyclobenzaprine) may help with your pain control and minimize your need for narcotic medications, but there is no guarantee that this will be the case. Your pain management might not get better while you are in this study.

The study doctors hope the information learned from this study will benefit you and other patients with a hysterectomy in the future. Information from this study might help researchers to come up with new medication protocols to help others in the future.

You will not receive any monetary compensation if the information from this study results in publication or new product development.

WHAT OTHER CHOICES ARE THERE IF I DO NOT TAKE PART IN THIS STUDY?
You do not have to take part in this research study in order to receive treatment. Your participation is voluntary. You may refuse to take part, or stop participating at any time without penalty, or jeopardizing your continued medical care at ChristianaCare, or lose benefits you would otherwise be entitled to.

Instead of being in this study, you have the option to continue with the routine preoperative medications for patients at ChristianaCare. If you are not a participant of the study, you may request cyclobenzaprine be added to your postoperative pain management plan.

WHAT ABOUT CONFIDENTIALITY?
We need to collect information about you to conduct this study. Your personal health information is health information about you that could be used to identify you. This information may include demographics (such as your age, sex, height, and weight), information about your health now and in the past, and other facts about you collected for the purposes of this research study. The information that will be collected will be the minimum needed to meet the goals of this research study and will be used only for the study described in this consent. If you decide not to allow this use of your information, you may not take part or continue to take part in the research study, since the researcher needs this information to meet the study goals.

We try to keep your personal health information private and confidential. We will use REDCap to collect information for the study. REDCap is a secure online system used by researchers to collect and store information for studies. It helps keep your data organized, secure, and private. Only the research team can access the information you provide, and it is stored safely so that your personal details are protected. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law and it may be disclosed to others as described in this section.

Individuals and organizations that may look at and/or copy your research records to conduct this research, assure quality of the data and analyze the data include:

- Members of the research team at ChristianaCare;
- Medical staff who are directly or indirectly involved in your care related to this research;
- People who oversee or evaluate research and care activities at ChristianaCare, including the ChristianaCare Institutional Review Board, a committee that reviews research projects to help protect the rights of research participants are protected; and
- People from agencies and organizations that perform independent accreditation and oversight of research, such as the Department of Health and Human Services, Office for Human Research Protections.

By signing this document, you are authorizing ChristianaCare to use and release your health information for this research. Some of these groups listed above may not be required to protect your information. If permitted by law, they may be allowed to share it with others without your permission.

The information from this study may be published in scientific journals or presented at scientific meetings but you will not be personally identified in these publications and presentations, as only aggregate information will be presented.

You have the right to see any medical information about yourself. However, during the research study you will not have access to all of the health information that is created or collected during the study. You do not have the right to review and/or copy records kept by the researchers associated with the study. This authorization will never expire.

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 still includes a summary of the results. You can search this Web site at any time.

WHAT ARE THE COSTS?

Taking part in this study may lead to added costs to you or your insurance company including costs for requiring additional cyclobenzaprine. You or your insurance company will be charged for continuing medical care and/or hospitalization if you have an adverse reaction to cyclobenzaprine. Please ask about any expected added costs or insurance problems.

Routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company.

In the case of injury or illness resulting from this study, emergency medical treatment is available but will be provided at the usual charge. No funds will be offered to compensate you in the event of injury. However, by signing this document, you are not giving up any right you have to pursue legal remedies for injury resulting from participation in this study.

WILL I GET PAID FOR BEING IN THIS STUDY?
No. You will receive no payment for taking part in this study.

WHAT ARE MY RIGHTS AS A PARTICIPANT?
Taking part in this study is voluntary. You may choose not to take part or may leave the study at any time. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide not to take part in the study, you will continue to receive the usual medical care appropriate for your condition. However, if you are thinking about stopping, we encourage you to talk to the researcher and your regular doctor first. They will tell you how to stop safely. You will neeed to consult your specific surgeon and/or the Primary Investigator prior to withdrawing. If you suddenly withdraw from the study, you may notice a change in your pain control. We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, contact the researcher Dr. Margaret Wingo at 302-623-4410.

For questions about your rights as a research participant, contact the ChristianaCare Institutional Review Board at (302) 623-4983.

You will be given a copy of this form upon submission. You may download it at the time of completion, but it will also be emailed to you securely.

By signing this form, you are allowing the research team, which includes the investigators listed on this form and other personnel involved in collating and analyzing the data to have access to the information described above.

SIGNATURE
You have read the information provided above. You voluntarily agree to take part in this study.

_____ _____
Signature of Research Subject Date

_____

Printed Name of Research Subject

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Legally Authorized Representative (LAR) Date

_____
Printed Name of LAR