CONSENT TO PARTICIPATE IN RESEARCH

AND

AUTHORIZATION FOR RELEASE OF
PROTECTED HEALTH INFORMATION

Improving Post-Operative Pain and Recovery in Gynecologic Surgery

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Protocol ID: 2019.08.20.MB
ClinicalTrials.gov ID: NCT04175509

INTRODUCTION

You are being asked to take part in a research study. The following information is being given to you to explain the purpose of the study, what you will be asked to do as a participant, and the potential risk and benefits. It will also explain that you do not have to participate in this study to receive medical care. You are encouraged to ask questions before deciding whether you wish to participate, or at any time during the course of the study. You will be told of any new findings that may influence your decision to continue to participate.

We understand that information about you and your health is personal. We are committed to protecting the privacy of that information. Because of this commitment, we must obtain your authorization before we may use or disclose your protected health information for the purposes of this clinical trial. This form provides that authorization and helps us make sure that you are properly informed of how this information will be used or disclosed. Please read this information carefully before signing this form.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to demonstrate that rectal acetaminophen is not inferior to intravenous acetaminophen in managing pain following major gynecologic surgery.

HOW DOES THIS STUDY DIFFER FROM THE WAY POST-OPERATIVE PAIN IS NORMALLY MANAGED?

Opioids, such as Oxycodone and Morphine are frequently used to manage post-operative pain. More recently, health care providers have been utilizing non-opioid medications,

such as acetaminophen, to help with post-operative pain. This study allows patients to receive opioid pain medication in a similar fashion as patients not enrolled in the study. However, patients enrolled in the study will not have access to additional non-opioid medications, such acetaminophen or ibuprofen during their first 24 hours post-op of your hospital stay . All other aspects of your care will be the same as patients not enrolled in the study. All the medications used in this study are already FDA approved and commonly used for post-operative pain.

WHO CAN TAKE PART IN THIS STUDY?

You are being asked to take part in this study because you have been scheduled for a hysterectomy via a minimally invasive approach.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Approximately 40 patients will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

BEFORE YOU BEGIN THE STUDY…

The study purpose and procedures will be explained to you by one of the research team members. If you decide to participate, you will be required to read this consent in its entirety and sign where indicated. Your past and present medical history will be reviewed for eligibility to participate in this study. A chemistry panel to evaluate liver enzymes will be included in your pre-operative laboratory studies.

DURING THE STUDY…

If you are eligible, you will then be "randomized".

Randomization is a standard procedure used in clinical trials where subjects are assigned by chance to one study group or another. It is used to make sure that the results of the study are not influenced by the selection of subjects/patients in one group as compared to the other. This is important to make certain that study results are accurately interpreted and therefore beneficial to future patients. In this study, you have a 50% chance of being assigned to one group or another.

Group 1: Rectal acetaminophen

Patients randomized to this group will undergo surgery at Aultman Hospital as scheduled by their physician. Patients randomized to this study group will receive rectal acetaminophen at the end of surgery prior to waking up from anesthesia. Patients will be prescribed oral Oxycodone as needed to manage post-operative pain. Oxycodone is one of the active ingredients in brand name medications such as Percocet. Intravenous morphine (or alternate opioid) will also be available as

needed for pain that is not controlled with oral Oxycodone. You will not be able to receive additional non-opioid medications, such acetaminophen or ibuprofen during the first 24 hours post-op of your hospital stay.

Group 2: Intravenous acetaminophen

Patients randomized to this group will undergo surgery at Aultman Hospital as scheduled by their physician. Patients randomized to this study group will receive intravenous acetaminophen at the end of surgery prior to waking up from anesthesia. Patients will be prescribed oral Oxycodone as needed to manage post-operative pain. Oxycodone is one of the active ingredients in brand name medications such as Percocet. Intravenous morphine (or alternate opioid) will also be available as needed for pain that is not controlled with oral Oxycodone. You will not be able to receive additional non-opioid medications, such acetaminophen or ibuprofen during the first 24 hours post-op of your hospital stay.

HOW LONG WILL I BE IN THE STUDY?

Your participation in the study will begin when you sign this informed consent form and will end in 24 hours post-operatively or at discharge, whichever comes first.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the doctor if you are thinking about stopping or decide to stop.

WHAT ARE THE RISKS OF THE STUDY?

You may have complications while in the study. Everyone taking part in the study will be watched carefully for any complications and may be removed from the study if necessary. You should talk to your doctor about any complications that you have while taking part in the study.

Although all of these medications are commonly used for post-operative pain management, the following adverse effects are commonly seen:

Acetaminophen: rash and itching

Oxycodone: drowsiness, dizziness, itching, constipation, nausea, vomiting

Morphine: low heart rate, low blood pressure, drowsiness, dizziness, fever, confusion, itching, dry mouth, constipation, nausea, vomiting, urinary retention, pain at injection site, weakness, decreased respiratory rate and oxygen saturation

There is a possibility that other complications may occur. You will be monitored for the occurrence of complications and should report any unusual events to the study staff.

The study group to which you are assigned may prove to be less effective or have more side effects than the other study group.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

Taking part in this study may or may not improve your post-operative outcome. While doctors know that the use of non-opioid pain medication, such as acetaminophen, reduce the use and need for opioid medications, it is unknown whether rectal or intravenous acetaminophen are equally effective in managing pain following gynecologic surgery. We do know that the information from this study will help doctors learn more about helping to manage post-operative pain and improve overall recovery. This information could help future patients.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate and continue to receive standard care.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

Taking part in this study will not lead to any foreseeable added cost to you.

You will receive no payment for taking part in this study.

WHO CAN ANSWER MY QUESTIONS ABOUT THIS STUDY?

In the case of life-threatening emergencies, call 911 first. If you experience adverse events that are not life-threatening, contact Michaela Beynon, MD at 330-363-6242 or Sareena Singh, MD, at 330-904-1280 immediately.

Immediate and necessary care for research related adverse events will be provided at Aultman hospital if you are injured because of participation in this research project. Any cost associated providing this care not paid for by her insurance will be your responsibility. Aultman Hospital has not made arrangements to provide compensation for any injury you may suffer as a direct consequence of the non-negligent performance of the procedure as described above. However, by signing this form, you do not give up your right to seek payment for harm you receive while participating in the study.

Dr. Beynon and Dr. Singh, or any other physicians involved with the study will answer any questions you have about this study. These individuals are available to answer questions before, during, and after the study. They can be contacted at the Aultman

Medical Group-Gynecologic Oncology, 2600 Tuscarawas St SW, Suite 420 Canton, OH 44708, 330-994-1280.

. If you have any questions about your rights as a research subject, contact the Aultman Health Foundation Human Research Review Board in the Office of Research, 2600 6th St. SW, Canton, OH 44710 (330-363-6793) or e-mail HRRB@aultman.com. You may also contact them if you feel pressured to enroll or continue with participation in the study.

Description of this clinical trial will be available on http://clinicaltrials.gov, as required by US law. This website will not include any information that can identify you. At most, the website will include a summary of the study and the results. You can search this website at any time.

WHAT ARE MY RIGHTS IN THIS STUDY?

Your participation in this project is voluntary. If you agree to be in the study, you are free to change your mind at any time. Refusal to participate, or a decision to discontinue participation will involve no penalty or loss of benefits to which you are otherwise entitled. You may withdraw from this study whenever you want, and you still have access to healthcare at Aultman Health Foundation.

The quality of care you receive will be the same regardless of whether you participate or not. If you decide to withdraw, we ask that you contact Dr. Beynon in writing at the above address to ensure your well-being.

AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

WHAT WILL THE INVESTIGATORS TO DO MAKE SURE THAT THE INFORMATION COLLECTED WILL REMAIN SECURE?

Your privacy is very important to us and the researchers will make every effort to protect it.

You have rights regarding the privacy of your medical information collected prior to and in the course of this research study. These rights are protected by a federal law that requires the Aultman Health Foundation and its affiliated hospitals and clinics, researchers, health care providers and physicians to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health and conditions ("protected health information"). If you decide to participate in the research described in this consent form, your protected health information will be used and shared with others as explained below.

WHAT PROTECTED HEALTH INFORMATION ABOUT ME WILL BE USED OR SHARED WITH OTHERS DURING THIS RESEARCH?

To do this research study, we need your permission to collect and use some of your health information, or you cannot be in the study. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the study.

The health information to be collected and used for this study is:

- Existing medical records;
- New health information created from study related tests, procedures, visits, and/or questionnaires;
- Demographic information [name, address, telephone number] or numbers or codes that will identify you, such as your social security number and medical record number;
- The history and diagnosis of your disease;
- Specific information about the treatments you received, including previous treatment(s) you may have had;
- Information about other medical conditions that may affect your treatment;

- The results of physical exams [blood pressure reading, heart rate, breathing rate, and temperature], laboratory blood test results, CT scans, MRIs, x-rays, pathology results, other diagnostic and medical procedures, as well as your medical history;
- Information on side effects you may experience and how these were treated;
- Long term information about your general health status and the status of your disease;
- Data that may be related to tissue and/or blood samples that may be collected from you;
- Family medical history;
- Allergies;
- Information about current and past medications or treatments.

For this study, we will collect and use your entire medical history.

WHY WILL PROTECTED HEALTH INFORMATION [PHI] ABOUT ME BE USED OR SHARED WITH OTHERS?

The main reasons include:

- To conduct and oversee the research described in the section, "WHAT IS INVOLVED IN THE STUDY?" and for all purposes necessary to conduct and ensure the integrity of the study.
- To ensure the research meets legal, institutional, and accreditation requirements; and
- To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm).

Other reasons may include for treatment, payment or health care operations. For example, some medical information produced by this study may become part of your hospital medical record because the information may be necessary for your medical care.

WHO WILL USE OR SHARE PROTECTED HEALTH INFORMATION ABOUT ME AT THE AULTMAN HEALTH FOUNDATION?

We will make every reasonable effort to protect the information and keep it confidential. The only Aultman Hospital employees allowed to handle your health information are those on the study team, and the Aultman Human Research Review Boards and Aultman officials who review the research plan and check the research activities to make sure the hospital's rules are followed.

Dr. Beynon and her study team will use and share your protected health information with:

- The Aultman Health Foundation Human Research Review Board, the committee that oversees research at this Institution;
- We may record your research information, including results of tests and procedures done for research, in your Aultman Hospital medical record. As a result, this research information may be seen by authorized members of the Aultman Hospital workforce who need to access your medical record in the performance of their duties (for example, to provide treatment, to ensure integrity of the research, accounting or billing matters, etc.)

WILL MY PROTECTED HEALTH INFORMATION BE SHARED WITH PEOPLE OUTSIDE THE AULTMAN HEALTH FOUNDATION?

We may share your information with people who do not work at Aultman Hospital because they planned, pay for, or work with us on this study. The Federal Privacy Rule may no longer protect your health information once it leaves Aultman Hospital. For this study, we plan to share information with those doctors, researchers or government representatives working with us on this study at the institutions or companies listed here:

- Your insurance company

WHAT ARE THE RISKS OF SHARING THIS HEALTH INFORMATION?

One risk of taking part in a research study is that more people will handle your personal health information collected for this study. While the study team makes every effort to keep the information confidential, an unauthorized person might see it. Depending on the kind of information being collected, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the study doctor about whether this could apply to you.

HOW LONG WILL PROTECTED HEALTH INFORMATION ABOUT ME BE USED OR SHARED WITH OTHERS?

There is no scheduled date at which time your protected health information that is being used or shared for this research will be destroyed. Research is an ongoing process.

MAY I HAVE ACCESS TO MY MEDICAL INFORMATION THAT RESULTS FROM MY PARTICIPATION IN THIS RESEARCH STUDY?

In accordance with the Aultman Health Foundation Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

During your participation in this study, you will have access to your medical record and any study information that is part of that record.

STATEMENT OF PRIVACY RIGHTS

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to **Michaela Beynon, MD** at **Department of Obstetrics and Gynecology, Aultman Hospital, 2600 6th St SW Canton, Ohio 44710**. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we may decide that you cannot continue to be part of the study. We may still use the information we have already collected.

You have the right to limit the use and sharing of your PHI, and you have the right to see your medical records and know who else is seeing them.

You do not have to give this permission for use of your PHI. If you decide not to provide permission, you will not be able to participate in this research study.

PUBLICATION OF RESULTS OR USE FOR TEACHING PURPOSES

The information from this study may be published in scientific journals or presented at scientific meetings but your identity will be kept strictly confidential. Your name or other identifiers will not be used in any publication or teaching materials without your specific permission.

CONSENT TO PARTICIPATION IN

By signing my name below, I confirm the following

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The study's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the study team use and share the health information and other information gathered for this study.
- I voluntarily agree to participate in this research study. I agree to follow the study procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will be given a copy of this signed document for your records. A second copy will be kept together with the Investigator's research records on this study. A third copy will be placed in your Aultman Hospital medical record.

Please keep it where you can find it easily. It will help you remember what we discussed today.

Research Participant's Name [PRINT]:

Research Participant's Signature: Date/Time

INVESTIGATORS CONFIRMING STATEMENT

I have given this research subject information on the study, which in my opinion is accurate and sufficient for the subject to understand fully the nature, risks and benefits of the study, and the rights of a research subject. There has been no coercion or undue influence.

INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT Date

I have explained the purpose of the research, the study procedures, identifying those that are investigational, the possible risks and discomforts and potential benefits. I have answered any questions regarding the research study to the best of my ability.