UNIVERSITY of ROCHESTER MEDICAL CENTER

Efficacy of IV Acetaminophen Versus Oral Acetaminophen

INFORMED CONSENT FORM

NCT03365622

Date: 1-13-2023

CONSENT FORM

Randomized, Double-Blind Clinical Study Evaluating Efficacy of Intravenous versus Enteric Acetaminophen in Donor Nephrectomy and Robot-Assisted, Laparoscopic Nephrectomy

Principal Investigator: Joseph Dooley, MD

This consent form describes a research study, what you may expect if you decide to take part and important information to help you make your decision. Please read this form carefully.

The study staff will explain this study to you. Please ask questions about anything that is not clear before you agree to participate. You may take this consent form home to think about and discuss with family or friends.

- Being in this study is voluntary – it is your choice.
- If you join this study, you can change your mind and stop at any time.
- If you choose not to take part, your routine surgical care will not be changed in any way.
- There are risks from participating and you should understand what these mean to you.

Introduction

You are being asked to take part in this study because you are scheduled for laparoscopic nephrectomy procedure (removal of your kidney).

Purpose of Study

Adequate pain control after surgery is important in your recovery. The purpose of this research study is to evaluate whether acetaminophen (also known as Tylenol), given by mouth (oral) or injected into your vein (intravenous), is more effective in controlling your pain after surgery. The use of acetaminophen will be in addition to the narcotic pain medications that your provider may prescribe for you during your hospitalization.

This study is being conducted by Dr. Joseph Dooley at the University of Rochester's Department of Anesthesiology.

Description of Study Procedures

No study related procedures will start until after you have had all of your questions answered and signed this informed consent form. Your pre-anesthesia evaluation will be conducted per standard of care, in preparation for your upcoming surgery.

If you decide to take part in this study, you will be randomly assigned, like flipping a coin, to either receive:

1) intravenous (IV) acetaminophen and placebo oral pills;

OR

2) placebo IV solution and oral acetaminophen medications.

A placebo is a substance that looks like the study drug but doesn't include any active ingredients.

The study medication will be given to you prior to your surgery and every six hours for the first 24 hours after surgery.

Neither you nor your doctors will know which treatment you are assigned to. If there is an emergency, the study team will be able to find out quickly which group you were assigned to.

In the recovery room and when transferred to a surgical inpatient unit, you will be asked to rate your surgical pain level and begin use of an incentive spirometer (a device used to keep your lungs healthy after surgery) per standard of care. You will be asked to rate your pain level before and after you use the incentive spirometer.

As needed, you will be able to receive other non-acetaminophen pain medications as ordered by your surgical team as standard post-surgical care.

Study staff will collect information from your medical record about your surgery, anesthesia, and post-operative care as it pertains to this research study.

Information about your study participation and study results may be included in your electronic health record. If you have concerns about this or to obtain more detail, you should discuss this with the study team.

Number of Subjects

Approximately 265 subjects will take part in this study.

Duration of the Study

Your participation in the study will last until 1day (24 hours) after your surgery.

Risks of Participation

Acetaminophen (Tylenol) is currently used pre-, intra-, and post-operatively with various surgical procedures. The most common side effects are nausea, rash and headache. Rare but serious side effects that may occur are severe skin rash, shortness of breath, chest pain, low red cell or platelet cell count and acute liver damage or failure. You will be monitored throughout the post-surgical time and any potential side effects will be evaluated and treated as standard of care. If you have any concerns about potential side effects of the study medication please discuss this with the study team.

Because this study involves collecting personal, identifiable information about you, there is a potential for invasion of privacy or breach in confidentiality. To minimize this risk, we will assign you a study number instead of labeling the information we collect from you with your name [or medical record number]. All of the information we collect will be stored in a secure manner and only study team members will have access to it.

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.

The study team may be notified if you receive other health care services at URMC or its Affiliates (e.g., visit to the emergency room). In addition, the following individuals may know you participated in research and may see results of testing conducted for this study:

- Staff at the University of Rochester Medical Center and its Affiliates (e.g., Strong Memorial Hospital, Highland Hospital, URMC primary care, specialist physician offices) who have a reason to access your electronic health record.
- Health care providers who are involved in your care at a facility that is not part fo the University of Rochester Medical Center and its Affiliates and who have reason to access your electronic health record.
- Individuals who request a copy of information from your health record for activities such as treatment or payment (e.g., medical insurance companies, worker's compensation).

Benefits of Participation

You might not benefit from being in this research study. The potential benefit to you might be improved pain control post operatively.

Costs

There will be no cost to you to participate in this study. All study medications will be covered under this research protocol.

Payments
You will not be paid for participating in this study.

Compensation for Injury
If you are directly injured by the drug being studied, or by medical procedures needed because of this study, and you receive medical care for the injury, you may need to pay for that care. You will be reimbursed for reasonable and necessary medical costs for such care, but you might not be reimbursed for care covered and paid for by a third party like your health insurance provider, or costs such as required co-payments or deductibles related to that coverage. No other funds have been set aside to pay for such things as lost wages or expenses due to a current underlying illness or condition.

If your research injury is paid for by the University, we will collect your name, date of birth, gender, and Medicare Health Insurance Claim Number or Social Security Number to determine your Medicare status. This information will be used only in accordance with the law. If you are a Medicare beneficiary, information about the study you are in, and any payments made related to your injury, will be reported to the Centers for Medicare & Medicaid Services (CMS), in accordance with CMS requirements. This information will not be used for any other purpose.

Confidentiality of Records and Authorization to Use and Disclose Information for Research Purposes

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will not collect personally identifying information for analysis and will assign you a unique patient identifier, like a numbered code. In order to collect data from your medical record, only study personnel who are trained to do human subject research will access this information. All study information will be stored in a password protected location. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or the study sponsor.

If you have never received a copy of the University of Rochester Medical Center (URMC) and Affiliates Notice of Privacy Practices, please ask the investigator for one.

What information may be used and given to others?
The study doctor will get your personal and medical information. For example:

- Research records
- Records about phone calls made as part of this research

- Records about your study visits
- Past and present medical records related to the study

Who may use and give out information about you?
- The study doctor and the study staff
- URMC and Affiliates

Your information may be given to:
- The Department of Health and Human Services
- The University of Rochester
- The U.S. Food and Drug Administration (FDA) may also need to inspect study records at some point during the study or even after it has been completed. In the event that this should occur, every effort will be made to keep identifying information about you private.

Why will this information be used and/or given to others?
- To do the research
- To study the results
- To see if the research was done correctly

If the results of this study are made public, information that identifies you will not be used.

What if I decide not to give permission to use and give out my health information?
Then you will not be able to be in this research study.

May I review or copy my information?
Yes, but only after the research is over.

How long will this permission be valid?
This permission will last indefinitely.

May I cancel my permission to use and disclose information?
Yes. You may cancel your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. Upon receiving the written notice, the study team will no longer use or disclose your health information and you will not be able to stay in this study. Information that has already been gathered may need to be used and given to others for the validity of the study.

May I withdraw from the study?

Yes. If you withdraw your permission to be in the study, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?
No. There is a risk that your information will be given to others without your permission.

Future Use of Information/Samples
Your information collected as part of this research will not be distributed or used for future research studies.

Return of Research Results
In general, we will not give you any individual results from your participation in the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Contact Persons
For more information concerning this research or if you feel that your participation has resulted in any research related injury, emotional or physical discomfort, please contact**:** Joseph Dooley, MD at (585) 275-2141.

Please contact the University of Rochester Research Subjects Review Board at 265 Crittenden Blvd., CU 420628, Rochester, NY 14642, Telephone (585) 276-0005 or (877) 449-4441 for the following reasons:

- You wish to talk to someone other than the research staff about your rights as a research subject;
- To voice concerns about the research;
- To provide input concerning the research process;
- In the event the study staff could not be reached.

Voluntary Participation

Taking part in this study is voluntary. You are free not to take part or to withdraw at any time, for whatever reason. No matter what decision you make, there will be no penalty or loss of benefit to which you are entitled. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner.
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SIGNATURES/DATES

After reading and discussing the information in this consent form you should understand:

- Why this study is being done;
- What will happen during the study;
- Any possible risks and benefits to you;
- Other options you may have instead of being in the study;
- How your personal information will be protected;
- What to do if you have problems or questions about this study.

Subject Consent

I have read (or have had read to me) the contents of this consent form and have been encouraged to ask questions. I have received answers to my questions. I agree to participate in this study. I have received (or will receive) a signed copy of this form for my records and future reference.

_____
Subject Name (Printed by Subject)

_____ _____
Signature of Subject Date

Person Obtaining Consent

I have read this form to the subject and/or the subject has read this form. I will provide the subject with a signed copy of this consent form. An explanation of the research was given and questions from the subject were solicited and answered to the subject's satisfaction. In my judgment, the subject has demonstrated comprehension of the information. I have given the subject adequate opportunity to read the consent before signing.

_____
Name and Title (Print)

_____ _____
Signature of Person Obtaining Consent Date