Department of Urology

NCT03058705
CONSENT FORM

Near Infrared Fluorescence Imaging for Bladder Cancer Detection

Principal Investigator: Edward Messing, MD, FACS

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 medical 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 have been diagnosed with bladder cancer or are suspected of having bladder cancer tumors and you are scheduled to undergo a transurethral resection of the bladder tumor (TURBT) surgery.

This study is being conducted by Dr. Edward M. Messing (Principal Investigator) of the University of Rochester, Department of Urology.

PURPOSE AND BACKGROUND OF STUDY

The purpose of this study is to (1) determine if an investigational light source can aid in taking a biopsy and diagnosing bladder cancer and (2) whether using an investigational light source can potentially reduce the time Cysview has to sit in the bladder.

Cysview is an FDA-approved drug that is instilled into the bladder to better identify bladder tumors while undergoing TURBT surgery. Currently, the Cysview is instilled into the bladder through a Foley catheter for approximately one hour before surgery.

During your surgery, the investigational light source will be used with a cystoscope and Cysview. The cystoscope is an FDA-approved instrument that allows visualization of your bladder and bladder tumors.

DESCRIPTION OF STUDY PROCEDURES

While in the operating room when you are under general anesthesia, Cysview will be instilled into your bladder using a Foley catheter. The Cysview will sit in your bladder for up to 10 minutes. Then the Cysview will be drained out of your bladder via the Foley catheter which will then be removed.

We will then insert the cystoscope into your bladder and use the investigational light source, which will be attached to the cystoscope, to view the interaction of Cysview and the bladder tumors. Use of the investigational light source might identify additional areas that the surgeon may want to biopsy.

Once we have obtained images of your bladder and any tumors, you will undergo your routine transurethral resection of bladder tumor (TURBT) surgery.

In addition, we will collect information about you from your medical record for the purposes of this research study.

NUMBER OF SUBJECTS

Locally, approximately 20 subjects will take part in this study.

DURATION OF THE STUDY

The study will begin and end on the day of your TURBT surgery.

RISKS OF PARTICIPATION

There are some risks to participating in this study.

Known adverse effects of the Cysview include headache or procedural pain (1%-10%), bladder spasms (2%), bladder pain, painful urination, blood in your urine (<10%). Abnormal urine tests (urinalysis) and inflammation of the bladder (cystitis) have been reported (<1%). A generalized allergy (anaphylaxis) causing fainting, low blood pressure, difficulty breathing, shortness of breath, hives, rashes, nausea or vomiting has occurred (<1%).

There are risks associated with foley catheter placement. The main risk of using a urinary catheter is that it can sometimes allow bacteria to enter the body. This risk is minimal because the catheter is only left for a short period of time, and placed in the sterile operating room. It is also possible to cause injury to the urethra (the tube that carries urine out of the body) when the catheter is inserted. This can cause future narrowing of the urethra because of scar tissue caused by catheter use.

There is no increased risk from the use of the investigational light source. All medications and equipment components in contact with you are FDA-approved for use in this patient group. Clinical engineering electrical safety certification will be performed. Cystoscopic light sources approved for human use will be used, but at reduced near infrared intensity for imaging purposes; so less energy is introduced into your bladder than would normally occur.

Privacy and Confidentiality:
There is a minimal risk of invasion of privacy and loss of confidentiality since study personnel will have access to the data that we collect about you. However, we will protect the privacy and confidentiality of your information by assigning you a code number. The database generated in this study will be kept secured in a password protected computer program at the University of Rochester Medical Center.

BENEFITS OF PARTICIPATION

You might not benefit from being in this research study, however, the reduction in dwell time may reduce unintended side effects by reducing the duration of mucosal contact with Cysview.

ALTERNATIVES TO PARTICIPATION

You do not have to participate in this study if you don't want to. Your TURBT surgery will be performed as part of standard care.

SPONSOR SUPPORT

The University of Rochester is receiving payment from Imagin Medical for the study drug (Cysview) and the use of the imaging equipment.

CONFLICT OF FINANCIAL INTEREST

[redacted], a sub-investigator on this study, is a co-inventor of the technology being studied, and therefore has a financial interest in the development of this technology. Please feel free to ask any further questions you might have about this matter.

COSTS

There is no cost to you for your participation in this study.

You and/or your insurance company will be responsible for paying for costs associated with your TURBT surgery (standard of care).

PAYMENTS

You will not be paid for participating in this study.

COMPENSATION FOR INJURY

If you are directly injured by the drug and device 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

The University of Rochester makes every effort to keep the information collected from you private. In order to do so, we will keep all collected data in a secured password-protected computer database program at the University of Rochester Medical Center. Sometimes, however, researchers need to share information that may identify you with people that work for the University, regulators or study sponsors. If this does happen we will take precautions to protect the information you have provided. Results of the research may be presented at meetings or in publications, but your name will not be used.

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
- Past and present medical records related to the study
- Results of medical tests related to the study (imaging)

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
- Imagin Medical
- 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 right

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.

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.

CONTACT PERSONS

For more information concerning this research, please contact the study coordinator at [redacted]. If you experience any of the potential side effects described in the "risks" section above or if you feel that your participation has resulted in any research-related injury, emotional or physical discomfort, please contact the study doctor, Dr. Edward M. Messing at [redacted] between 8am-5pm. After 5pm, call ([redacted] and ask for the urologist on-call.

You may also 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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SIGNATURE/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