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C07411
Subject: Consent to Participate in Research

Institute for Academic Medicine
Vandalia Health

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CAMC INSTITUTE FOR ACADEMIC MEDICINE (IAM)
INFORMED CONSENT TO PARTICIPATE IN RESEARCH

DATE: _____

PATIENT NAME:

CAMC Institute for Academic Medicine
CAMC Urology at Memorial
3100 MacCorkle Ave SE Unit 610
Charleston, WV 25304

RESEARCH INFORMATION AND CONSENT FORM

Study Title: Hyperthermic Irrigation Followed by Intravesical Chemotherapy in Non-Muscle Invasive Bladder Cancer

Protocol Number: 1357

Sponsor: West Virginia Clinical and Translational Science Institute

Investigator: Michael G. Stencel, DO

Phone : (304) 388-5280

Key Information

You are being asked to volunteer for research. Below is some key information to keep in mind when thinking about why you may or may not want to be in the research. Please ask the study doctor or the study staff to explain any words you do not clearly understand.

Introduction

The purpose of this form is to provide you with information that may affect your decision as to whether or not to participate in this research study. The person performing the research will answer any of your questions. Read the information below and ask any questions you might have before deciding whether or not to take part. If you decide to be involved in this study, this form will be used to record your consent. You must be at least 18 years of age to participate.

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Why am I being asked to take part in this research study?

You are being asked to take part in this study because you may be diagnosed with low- to intermediate-risk appearing non-muscle invasive bladder cancer (NMIBC) during your procedure. Your participation in this study is completely voluntary. You may refuse to participate or stop your participation in this research study at any time without penalty or loss of benefits and without jeopardizing your medical care at Charleston Area Medical Center, Inc. (CAMC).

Do you have to participate?

No, your participation is voluntary. You may decide not to participate at all or, if you start the study, you may withdraw at any time. Withdrawal or refusing to participate will not affect your relationship with CAMC in any way. If you would like to participate, sign and return this form to the principal investigator, Dr. Michael Stencel, or research study staff. You will receive a copy of this form.

Purpose of the Study

You have been asked to participate in a research study about a new way to treat bladder cancer. This treatment uses warm saline (HISA) during the surgery to remove tumor(s) from your bladder (TURBT). After removing the tumor(s) chemotherapy will be placed into your bladder. The purpose of this study is to see how safe this treatment is and how easy it is to use in caring for people with early-stage bladder cancer.

How long will it take?

This study will not require additional time during the TURBT procedure. There will be an additional 15 minutes during standard follow-up visits to complete a survey regarding your quality of life after your procedure.

What will you be asked to do?

If you agree to participate in this study, you will be asked to:

After giving your consent for the duration of the study (3 years), after giving consent, you will be randomly selected to have either heated or room temperature saline during the procedure and you will not know which treatment you receive but the physician will. This is known as Single Blinded Randomization and means you will be randomly assigned to one of the two treatments based on chance, like a flip of a coin. Neither you nor the researcher chooses your assigned group. You will have an equal chance of being in either group.

<u>Room temperature saline procedure description:</u>

The procedure is done under general anesthesia, so the patient does not feel pain. A rigid cystoscope (a thin tube with a camera) is gently passed through the urethra into the bladder. Your

doctor will carefully look at the inside of the bladder to find any tumors. The number, size, shape, and location of the tumors are noted. The bladder is filled with room temperature saline to stretch the bladder and allow a clear view. A small electrical loop is used to shave the tumor away in small pieces. Both the surface and the deeper tissue are removed. This helps make sure the tumor is fully removed and allows accurate staging (description of size of tumor and if it has spread). Any bleeding areas are sealed using heat. The removed tumor and deeper tissue samples are sent to the lab for testing. Testing these samples help determine how deep the cancer has grown. The bladder is checked again to make sure all visible tumor tissue has been removed. If needed, more tissue may be taken. A single dose of chemotherapy may be placed directly into the bladder after surgery.

Heated temperature saline procedure description:
The procedure is done under general anesthesia, so the patient does not feel pain. A rigid cystoscope (a thin tube with a camera) is gently passed through the urethra into the bladder. Your doctor will carefully look at the inside of the bladder to find any tumors. The number, size, shape, and location of the tumors are noted. The bladder is filled with heated saline to stretch the bladder and allow a clear view. A small electrical loop is used to shave the tumor away in small pieces. Both the surface and the deeper tissue are removed. This helps make sure the tumor is fully removed and allows accurate staging (description of size of tumor and if it has spread). Any bleeding areas are sealed using heat. The removed tumor and deeper tissue samples are sent to the lab for testing. Testing these samples help determine how deep the cancer has grown. The bladder is checked again to make sure all visible tumor tissue has been removed. If needed, more tissue may be taken. A single dose of chemotherapy may be placed directly into the bladder after surgery.

If selected for the heated saline it is not expected to add more time to the procedure.

After your procedure, you will have follow-up visits around 2 weeks, 3 months, and 6 months, and then every 6-12 months for up to 3 years; or until your cancer returns, worsens; you choose to leave the study, or you pass away. At these visits, we will check your health with a physical exam, review your symptoms, and perform tests such as cystoscopy (looking inside the bladder), urine tests, and urine cultures if needed. You will also complete questionnaires about your quality of life and how your bladder cancer affects you. During each visit, the study team will provide counseling, answer questions, and help you understand your care and surveillance plan.

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Schedule of events and study visits

Schedule of Events				
Procedures	**Baseline**	**Postoperative Visit (up to 4 weeks postop)**	**3-month Visit (+/- 2 weeks)**	**6-month visit and all visits after 6 months (+/- 2 weeks)**
Urinalysis	X	X	X	X
Urine culture	X	X	X	X
Cystoscopy	X		X	X
TURBT with normothermic or hyperthermic saline irrigation	X			
Questionnaires	X	X	X	X

What are the risks involved in this study?

The risks that are common with participation in this study with heated and room temperature saline include the following:

- Urinary tract infection
- Burning when you urinate
- Needing to urinate more often or urgently
- Blood in the urine
- Bladder pain or discomfort

These are rare risks that are involved with participation in this study with heated and room temperature saline include the following:

- Injury to nearby organs or tissue
- Sepsis
- Bladder spasms
- Trouble emptying the bladder
- Narrowing of the urine tube (urethra)

- Hole in the bladder (perforation)
- Severe bladder irritation
- Allergic reaction to cancer chemotherapy drug or anesthesia
- Cancer chemotherapy drug entering the bloodstream
- Breathing problems, nausea, or allergic reactions to anesthesia

All treatment is done in a medical setting with trained doctors, including urologists and anesthesia specialists. Emergency care is available right away if needed.

You may not be able to receive this treatment if you have any of the below:

- A hole or tear in your bladder
- Heavy bleeding in your urine
- An active urinary tract infection
- A known allergy to the medication gemcitabine

What are the possible benefits of this study?
The possible benefits of participation are that participants will have access to a new potential therapy that may improve control or reduce recurrence, delayed progression, or improved bladder preservation beyond standard intravesical therapy. The participants will be managed by a multidisciplinary research team, which may offer a higher level of attention or coordinated care.

You may not receive any direct benefit from participating in this study; however, there may be societal benefits such as contribution to medical knowledge by helping the research team gather essential information for safety, feasibility, and preliminary efficacy data.

Is there an alternative to participation?
All patients will receive standard of care TURBT and intravesical gemcitabine. Alternatives include observation in select cases, induction/maintenance intravesical chemotherapy, or Bacillus Calmette-Guerin depending on risk category. Patients may decline participation and receive guideline-concordant NMIBC management without affecting their care.

Will participating in the study cost you anything?
Research-required tests or procedures which are considered routine care (meaning you would receive the tests whether or not enrolled in the study) will not be covered by the sponsor, CAMC, or CAMC Institute for Academic Medicine (CAMC IAM) and will be the responsibility of you and/or your insurer. You will be responsible for all co-pays and deductibles associated with routine care billable to insurance and/or yourself.

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If you were harmed while participating in the study, who would pay for the necessary medical care?
In the case of injury or illness resulting from this study, emergency medical treatment is available from CAMC.

The fact that you are voluntarily participating in this research study does not guarantee you will receive monetary compensation or payment for the costs associated with research-caused side effects or complications.

For more information concerning this research study and related risks or injuries, you may talk with your study doctor at (304) 388-5280 or a member of the study team at (304) 388-9923.

Signing this consent form does not waive or limit your legal rights.

Will there be any travel or other study-associated costs (for example, childcare) and will researchers provide any money to cover those costs?
No. You will not be reimbursed for any study-associated costs, such as travel, hotel, childcare, meals, etc. You will be responsible for covering these costs.

Will I be paid for taking part in this research?
No, you will not be paid for taking part in this research.

How will my information be protected?
We will make every effort to protect the confidentiality of study records that identify you, but we cannot guarantee total confidentiality. Your information will be viewed by the research team and other people affiliated with CAMC who help administer and oversee research. People outside of CAMC may also need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study, and organizations that sponsor or help conduct the study. If information from this study is published or presented at scientific meetings, your name and other identifiable information will not be used.

Whom to contact with questions concerning your rights as a research participant?
For questions about your rights or any dissatisfaction with any part of this study or if you wish to offer input, you can contact, anonymously if you wish, the Officer for Research Integrity at (304) 388-9913.

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What are the reproductive risks?

You should not be pregnant or father a child within 2 weeks of treatment. If you are pregnant, you cannot take part in this study. If you and your sexual partner are capable of becoming pregnant, you are required to use effective birth control prior to treatment during this study.

Please notify the study doctor immediately if you think you or your partner is pregnant or if you become pregnant. If you are a female and of reproductive age, you will be required to have a pregnancy test performed before surgery.

The effects of hyperthermic intravesical saline during TURBT on an unborn child are not known, and it is not known whether taking this drug now can have effects on unborn children.

TURBT carries minimal direct reproductive risk; however, anesthesia exposure, perioperative medications, and adjunctive intravesical therapies (e.g., BCG, mitomycin C, gemcitabine) may pose fetal or teratogenic risks if pregnancy occurs around the time of treatment. TURBT is not known to impair fertility, and reproductive organ injury is rare.

Medications

You must give the study doctor a list of all the medicines you are taking and any known allergies to medications. This includes vitamins, minerals, herbal supplements, prescribed medications, and over-the-counter medications. This information will be used to reduce medication-related risks to you (e.g., drug interactions). Tell the study doctor if you change any of your medicines during the study.

Additional Information and Details

How will my information be protected?

In addition to the protections described above, we want you to know the following:

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 Web site at any time.

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Could my information be used for future research without asking for my additional permission?
Yes. If all identifiers (name, date of birth, etc.) are removed, it is possible that the data collected for this study may be used for future research studies or distributed to another investigator for future research studies without your additional consent.

Will you be given the results of any study tests or procedures that are done?
Participants will be notified of which treatment arm they received during their TURBT procedure by secure communication at the end of the study.

What will happen if you decide to withdraw from the study?
If you decide to leave the study, contact the researchers so they know. The researchers may ask you the reason, but you are not required to provide it.

If you want to volunteer to be in this research, please sign below.

Signature
You have been informed about this study's purpose, procedures, possible benefits and risks, and you have received a copy of this form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask other questions at any time. You voluntarily agree to participate in this study. You agree to allow the researchers to use and share your patient health information as described in this form. By signing this form, you are not waiving any of your legal rights.

Signature of participant Date

Signature of person obtaining or verifying consent Date

Witness Signature Date

(A witness signature is only required if the consent form is to be read to the subject. In all other instances, the witness signature should be left blank.)