COMPOUND AUTHORIZATION AND CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
200 FR. 4 (2016-2)

YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL

Study Title: *Toradol to Reduce Ureteroscopic Symptoms Trial (TRUST)*
Principal Investigator: *Piruz Motamedinia MD*
Funding Source: *Department of Urology*

Invitation to Participate and Description of Project

You are invited to take part in a research study designed to determine if a non-narcotic pain medication called ketorolac (Toradol) can help with pain during and following ureteroscopy. You have been asked to participate because we are inviting all adults who undergo ureteroscopy into this research study.

In order to decide whether or not you wish to participate in this research study you should know enough about its risks and benefits to make an informed decision. This consent form gives you detailed information about the study, which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, any risks of the procedures, possible benefits and possible alternative treatments. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

Ketorolac is a commonly used pain medication for patients with moderate to severe pain, often after surgery. It is a non-steroidal anti-inflammatory (NSAID) such as ibuprofen and is not a narcotic. We feel that the addition of ketorolac to the standard pain medications used in surgery may decrease the need for narcotics and potentially their side effects. Alternatively, ketorolac may provide no benefit to pain reduction during surgery. We need to perform a study to prove determine its effects and potential benefits. To do this, we will place participants into two groups – some who receive ketorolac and those who do not. The groups are selected randomly, as if by tossing a coin.

In one group, participants will receive standard pain medications used by their anesthesiologist during the procedure. In the other group, participants will receive standard pain medications along with one dose of ketorolac during the procedure. You and your surgeon will be blinded to whether or not you received ketorolac. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

Be assured that you will not be deprived of any necessary pain medication for the purposes of this study. Our goal is to determine if we can maximize patient comfort while minimizing unnecessary treatments and side effects.

Once you are home, you will be asked to fill out a survey that has questions related to pain. This will be filled out once a day for a total of 7 days following your procedure. In addition, you will be provided a pain medication form to record the amount of pain medication you need. This will also be done daily for a total of 7 days. We ask that you bring these forms with you during your first follow-up appointment. You may also mail or fax the surveys to our office.

Risks and Inconveniences

Risks from participating in this trial include those associated with the use of ketorolac. This includes but is not limited to gastrointestinal (gastric or intestinal bleeding or perforation), cardiovascular (stroke or myocardial infarction), renal (kidney failure), bleeding, and allergies, including anaphylactic shock.

Procedures Statements

The delivery of pain medications during ureteroscopy require the use of an intravenous (IV) line. This is a safe procedure used in every surgery requiring anesthesia. Your involvement in this study does not effect this.

The FDA approves ketorolac as an NSAID indicated for the short-term (up to 5 days in adults) management of moderately severe acute pain that requires analgesia at the opioid level.

Benefits

You may or may not personally benefit from participation in this trial, as you may not receive ketorolac as part of your ureteroscopy; however, the treatment group may experience decreased postoperative pain, decreased anesthetic requirements and decreased side-effects associated with anesthesia or ureteroscopy. In the future, the results of this study may be useful for guiding treatment strategies for other institutions involved in ureteroscopy procedures and for providing the best treatments to reduce postoperative pain following ureteroscopy.

Economic Considerations

You will not receive any payments for participating in this trial. Since ketorolac is commonly used in the peri-operative setting, costs of the drug are bundled into the billed amount for the specific procedure performed.

Treatment Alternatives/Alternatives

The alternative to this study is not to participate but instead proceed with the standard of care.

Confidentiality and Privacy

Any personal identifiable information that is obtained in connection with this study will remain confidential and will be disclosed only with your permission or as permitted by U.S. or State law. Examples of information that we are legally required to disclose include abuse of a child or elderly person, or certain reportable diseases. All research information will be stored in a locked file cabinet in principle investigators office, and on encrypted, password-protected laptop computers. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity unless your specific consent for this activity is obtained.

We understand that information about you obtained in connection with your health is personal, and we are committed to protecting the privacy of that information. If you decide to be in this study, the researcher will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name, age, and medical record number. This information will be de-identified at the earliest reasonable time after we receive it, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, and this link will be kept secure and available only to the PI or selected members of the research team. Any information that can identify you will remain confidential. This information will be stored on password-protected and encrypted workstations to prevent unauthorized access, and all hard-copies of these records will be stored in locked cabinets and offices.

The research team will only give this coded information to others to carry out this research study. The link to your personal information will be kept for the course of the study and completion of the manuscript, after which time the link will be destroyed and the data will become anonymous. The data will be kept in this anonymous form until it is destroyed upon completion of the study manuscript.

The information about your health that will be collected in this study includes:

- Research study records
- Medical records of only those services provided in connection with this study, including the study medications received intraoperatively
- Records about your study visits
- Pain questionnaire
- Pain medication log
- Ureteral Stent Symptom Questionairre

Information about you and your health which might identify you may be used by or given to:

- *The U.S. Department of Health and Human Services (DHHS) agencies*
- Representatives from Yale University, the Yale Human Research Protection Program and the Yale Human Investigation Committee (the committee that reviews, approves, and monitors research on human subjects), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- Those providers who are participants in the Electronic Medical Record (EMR) system.
- Those individuals at Yale who are responsible for the financial oversight of research including billings and payments
- The Principal Investigator Piruz Motamedinia
- Health care providers who provide services to you in connection with this study
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

By signing this form, you authorize the use and/or disclosure of the information described above for this research study. The purpose for the uses and disclosures you are authorizing is to ensure that the information relating to this research is available to all parties who may need it for research purposes.

All health care providers subject to HIPAA (Health Insurance Portability and Accountability Act) are required to protect the privacy of your information. The research staff at the Yale School of Medicine and Yale New Haven Hospital are required to comply with HIPAA and to ensure the confidentiality of your information. Some of the individuals or agencies listed above may not be subject to HIPAA and therefore may not be required to provide the same type of confidentiality protection. They could use or disclose your information in ways not mentioned in this form. However to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

You have the right to review and copy your health information in your medical record in accordance with institutional medical records policies. However, by deciding to take part in a single or double blinded treatment study and sign this permission form, you will not be allowed to look at or copy your study related information until after the research is completed.

This authorization to use and disclose your health information collected during your participation in this study will never expire.

In Case of Injury

If you are injured while on study, seek treatment and contact the study doctor as soon as you are able.

Yale School of Medicine and Yale-New Haven Hospital do not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.

You do not give up any of your legal rights by signing this form.

Voluntary Participation and Withdrawal

Participating in this study is entirely voluntary. You are free to choose not to take part in this study. Refusing to participate will involve no penalty or loss of benefits to which you are otherwise entitled (such as your health care outside the study, the payment for your health care, and your health care benefits). However, you will not be able to enroll in this research study and will not receive study procedures as a study participant if you do not allow use of your information as part of this study.

If you do become a subject, you are free to stop and withdraw from this study at any time during its course. To withdraw from the study, you can speak with a member of the research team at any time and tell them that you no longer want to take part. You will be withdrawn from the study immediately and you will not receive Ketorolac during your procedure or be asked to provide any study related surveys.

The researchers may withdraw you from participating in the research if necessary. Such conditions include but are not limited to allergic reactions or abnormal bleeding.

If you do choose not to participate or if you withdraw from this study, it will not harm your relationship with your own doctors or with Yale-New Haven Hospital.

Withdrawing Your Authorization to Use and Disclose Your Health Information

You may withdraw or take away your permission to use and disclose your health information at any time. You may withdraw your permission by telling the study staff or by writing to

Piruz Motamedinia, M.D.
PO Box 208058
New Haven, CT 06520-8058

When you withdraw your permission, 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 until the end of the research study, as necessary to insure the integrity of the study and/or study oversight.

Questions

We have used some technical terms in this form. Please feel free to ask about anything you don't understand and to consider this research and the consent form carefully – as long as you feel is necessary – before you make a decision.

Authorization and Permission

I have read (or someone has read to me) this form and have decided to participate in the project described above. Its general purposes, the particulars of my involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

By signing this form, I give permission to the researchers to use [and give out] information about me for the purposes described in this form. By refusing to give permission, I understand that I will not be able to be in this research.

Name of Subject:_____

Signature:_____

Date:_____

_____ _____
Signature of Principal Investigator Date

or

_____ _____
Signature of Person Obtaining Consent Date

If after you have signed this form you have any questions about your privacy rights, please contact the Yale Privacy Officer at 203/432-5919.

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator, *Piruz Motamedinia, PO Box 208058, Department of Urology, Yale School of Medicine, New Haven, CT 06520-8058*. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions you may have concerning this research, or to discuss your rights as a research subject, you may contact the Yale Human Investigation Committee at (203) 785-4688. You may also reach out to our urology staff at 203-785-2815.