# Permission to Take Part in a Human Research Study

**NCT05082142**

## Tranexamic Acid to Improve Same-day Discharge Rates After Holmium Laser Enucleation of the Prostate (HoLEP)

**10/29/2021**

## Consent

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Title of Research Study: Tranexamic acid to improve same-day discharge rates after Holmium Laser Enucleation of the Prostate (HoLEP)

Investigator: Amy Krambeck, MD

**Supported By:** This research is supported by the Department of Urology.

**Financial Interest Disclosure:** The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study: Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

**Key Information:**
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

## Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you are undergoing holmium laser enucleation of the prostate (HoLEP).

## What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

## Why is this research being done?
The purpose of this study is to determine if there is a significant difference in bleeding for patients who receive a drug referred to as TXA (tranexamic acid) during surgery. TXA is a medication that works by slowing the breakdown of blood clots, which helps to prevent prolonged bleeding.

We seek to assess differences in same day discharge and same day catheter removal rates after surgery between men who do and do not receive TXA. We will also assess whether the rate of complications from surgery such asd deep venous thrombosis and pulmonary embolism are reduced for individuals who receive TXA .

## How long will the research last and what will I need to do?
We expect that you will be in this research study for 3 months.

Before your surgical procedure, you will be randomly put in one of two groups by chance (like the flip of a coin). One group will receive TXA continuously during surgery. The other group will not receive TXA during surgery..

If you choose not to participate in this study, you will not receive TXA during your surgery. Currently, TXA is not routinely given during HoLEP. However, TXA is commonly used in orthopedic, cardiac, otolaryngologic and gynecologic surgeries.

You will be asked to complete surveys after your surgery about if you are experiencing difficulty with urinated or blood in the urine.

More detailed information about the study procedures can be found under the section **What happens if I say "Yes, I want to be in this research"?**

## Is there any way being in this study could be bad for me?

Your HoLEP surgical procedure will not be different from the treatment you would receive if you were not in this study.

Side effects of TXA may include nausea, vomiting, diarrhea, and muscle pain.

More detailed information about the risks of this study can be found under **"Is there any way being in this study could be bad for me? (Detailed Risks)"**

## Will being in this study help me any way?

***There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include a reduction in potential side effects following HoLEP.***

## What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.

Your alternative to participating in this research study is to not participate.

**Detailed Information:**
The rest of this document includes detailed information about this study (in addition to the information listed above).

## Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to Matthew Lee at matthew.lee@nm.org.

This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.

- You want to get information or provide input about this research.

## How many people will be studied?
We expect about 110 people here will be in this research study.

## What happens if I say "Yes, I want to be in this research"?
If you agree to be in the study, you will do the following things:

Before your surgical procedure, you will be randomly put in one of two groups by chance (like the flip of a coin). One group will receive TXA during surgery. The other group will not receive any TXA during surgery.

If you choose not to participate in this study, you will receive no TXA during your procedure.

After your surgery, you will receive weekly surveys asking you to report any instances of difficulty urinating or blood in the urine. These surveys will be sent to you via text message. Normal messaging rates will apply. If you do not want to receive the survey via text,, a research coordinator will contact you via phone. Those will continue for 12 weeks.

At your standard clinical follow up appointment (30 days after surgery), you will be asked to complete a questionnaire about bleeding compications and symptoms.
At your 12 week follow up appointment you will be assessed for benign prostate hyperplasia (BPH) symptoms and your urine flow rate will be measured.

## What happens if I say "Yes", but I change my mind later?
You can leave the research at any time; it will not be held against you.

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, please contact Dr. Amy Krambeck at amy.krambeck@northwestern.edu, or tell any member of the research team.

Your participation may be terminated by the investigator without regard to your consent in the following circumstances: you do not have surgery as planned to treat your BPH. .

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. Specifically, your choice not to be in this study will not negatively affect your right to any present or future medical treatment.

## Detailed Risks: Is there any way being in this study could be bad for me?
Side effects of TXA may include nausea, vomiting, diarrhea, and muscle pain. In addition, you may feel uncomfortable answering questions included in the survey. While completing the survey, you can tell the researcher that you feel uncomfortable or do not want to answer a particular question.

This study involves the use of your identifiable, personal information and there is a chance that a loss of confidentiality could occur. The researchers have procedures in place to lessen the possibility of this happening. See the section below titled: **"What happens to the information collected for the research?".**

To minimize these risks, the following actions will be taken:

- While completing the survey, you can tell the researcher that you feel uncomfortable or do not care to answer a particular question.
- We will keep all study related information in a secure database that is only accessible to study personnel.

## Will it cost me anything to participate in this research study?

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

## Will being in this study help me in any way?

***There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include a reduction in potential side effects following HoLEP.***

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution and the Food and Drug Adminitration (FDA).

The sponsor, monitors, auditors, the IRB, the Northwestern University Office of Research Integrity, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protection (OHRP), and the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

## Data Sharing

De-identified data from this study may be shared with the research community at large to advance science and health. We will remove or code any personal information that could identify you before files are shared with other researchers to ensure that, by current scientific standards and known methods, no one will be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

## What else do I need to know?

If you become ill or are injured as a result of this study (medications, devices or procedures), you should seek medical treatment through your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury.

The hospital [university, researchers] will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

You will not be compensated for your participation in this study.

## HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests, or certain health information indicating or relating to a particular condition as well diaries and questionnaires
- Records about study medication or drugs
- Records about study devices

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.
- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will expire at the end of the research study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

PI's Name: Amy Krambeck, MD
Institution: Northwestern University
Department: Urology
Address: 676 N St. Clair St
Chicago, IL, 60611

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

## Signature Block for Capable Adult:

## Permission to Take Part in a Human Research Study

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent