NCT04347122

Tranexamic Acid in Radical Resection and Endoprosthetic Reconstruction Protocol

Sept 8, 2022

KUMC CONSENT TEMPLATE FOR FDA-REGULATED STUDIES

RESEARCH CONSENT FORM

Tranexamic Acid in Radical Resection Endoprosthetic Reconstruction. A clinical trial
Protocol # 144738

Investigator: Kyle Sweeney, MD
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University of Kansas Medical Center
913-588-6100

- We are asking you to be in a research study.
- Research is done to answer a scientific question. Research studies may or may not help the people who participate.
- Joining this study is completely voluntary. If you say yes, you can quit the study at any time.
- You can still get medical care and other services from the University of Kansas Medical Center even if you are not in the study.
- The research team will explain what happens if you decide to join the study. This conversation is called “informed consent.”
- Informed consent includes a chance to get your questions answered before you make your decision. Please ask as many questions as you need to.
- This consent form explains the study. Take as much time as you need to decide.
- If you decide to be in the study, you will be asked to sign this form.

This research study will take place at the University of Kansas Medical Center (KUMC) with Dr. Kyle Sweeney as the researcher. About 140 people will be in the study at KUMC.

Why is this study being done?

The surgical procedure (a resection) used to remove a large bony and soft tissue tumor in people who have abnormal diseases of the primary bones typically causes a large amount of blood loss and requires the need for a blood transfusion. During the procedure Tranexamic acid (TXA) is an medication is used to reduce blood loss.

The purpose of this study is evaluate the use of tranexamic acid (TXA) in radical resection of soft-tissue tumors and bony tumors in the body. In doing this study researchers are hoping to learn if TXA will help in blood loss during surgery.

What is being tested in this study?

Tranexamic Acid (TXA) is given to stop or reduce heavy bleeding. It works by stopping clots from breaking down and by decreasing unwanted bleeding. TXA is FDAapproved usage for heavy menstrual bleeding and short-term prevention in patients with hemophilia.

How long will I be in the study?

We expect your participation to last the duration of your hospital stay. Should any complications arise during your routine follow-up after surgery, that visit will be noted as a part of this study.

What will I be asked to do?

If you choose to participate in this study, you will be randomly assigned to one of four groups. This means you will NOT know which group you have been assigned to.

You will be randomly assigned (like rolling the dice) to one of two groups, depending on what procedure you have.

- Group 1: bony tumor removal (10 minutes before and at the end of surgery, 1g TXA IV)
- Group 2: bony tumor removal (receives nothing)
- Group 3: soft tissue removal (10 minutes before and at the end of surgery, 1g TXA IV)
- Group 4: soft tissue removal (receives nothing)

You will have a 1 in 2 chance (50%) of receiving TXA. You will not know which treatment you are receiving. In the rest of this consent form, TXA be called “the study drug.”

Your care, including pre-operative requirements, operative procedure to remove the tumor, routine lab work and surgical drains, will not change by your participation in this study. The medication randomization will be the only changes in your care if you choose to participate in the study.

For the two groups receiving TXA, the first dose will be administered through IV prior to the start of your operation and the second dose will be administered at the end of surgery.

Patient care post-op will follow current standard of care regardless of study participation. The study team will collect information about your progress. Each follow up visit will be standard of care, which are usually around 2-3 weeks, 6 weeks, and 3 months post-op. Your total time of study participation will be approximately 4 to 6 months.

You will be asked to allow data to be collected from your physical exams and medical records, This information will be analyzed independently to detect any correlation with perioperative blood loss and transfusion rate

What are the possible risks or discomforts?
You may have problems because of TXA used in this study or because of the procedures that will be performed during the study. These are called adverse events or side effects. Some may be only an inconvenience, but some may be harmful. There could be side effects of TXA that are not yet known or the research may involve risks to you that are currently unforeseeable. TXA given intravenously is generally well tolerated, but has been reported to cause complications. It is important that you tell the study team immediately about any side effects or problems you have.

Rare but Serious – Deep Venous Thrombosis (DVT)

- Venous thromboembolism (VTE) rates are low (2%). This information is taken from a study that evaluated 1262 patients that were considered at high risk at 90 days postoperatively. A different study reviewed 1131 patients that were considered high risk and TXA was not considered associated with an increase in symptomatic thromboembolic events.

- Blood clot

Allergic Reaction Risks

Sometimes, people have serious allergic reactions to drugs. A severe allergic reaction could be life-threatening and may result in death. Symptoms of allergic reactions include:

- Difficulty breathing
- Rapid heart rate
- Itching
- Rash
- Redness
- Nausea
- Vomiting
- Dizziness
- Headache

You should call 911 if you think you are having a severe allergic reaction. Please also contact the study team if you have any of these or other side effects during the study.

Are there benefits to being in this study?
Researchers don't know if you will benefit from this study. If the study drug is effective, you may experience less blood loss during and after surgery. Participants randomized to the group that does not receive the TXA will not benefit.

Researchers hope that the information from this research study may be useful in the treatment of other patients with needing soft and bony tumors removed.

Will it cost anything to be in the study?
You will not be charged for being in the study. The exams, tests, surgery, study drug, and/or procedures performed in this study are part of the usual approach to manage your disease. These are considered "routine" and will not be paid for by the study, but will be charged to you or your insurance. If you have insurance, it is possible that it will not pay for these routine charges because they take place within a research study. You should talk to your insurance company and review your specific benefits and coverage before deciding to participate.

Some procedures require pre-authorization from your insurance company and representatives of the clinic or hospital will be helping you with that process. Preauthorization is not a guarantee of payment.

The University of Kansas Health System has a financial assistance program for patients who qualify. You will be charged for all charges that are not covered by the study, your insurance, or the financial assistance program. Financial Counselors from the University of Kansas Health System are available to review your expected costs, provide you with more information, and help you with any questions.

Will I get paid to participate in the study?
There is no payment for this study.

What happens if I get hurt or sick during the study?
If you have a serious side effect or other problem during this study, you should immediately contact Kyle Sweeney, MD at 913-945-7000If it is after 5:00 p.m., a holiday or a weekend, you should call 913-588-5000 and ask for the Orthopedic Surgery attending physician on call. Please tell the physician that you are in this research study. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a physical injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party. You will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

What other choices do I have?

You can choose not to be in the study. Instead of being in this study, you can receive treatment that is already available, such as tranexamic acid (TXA).

You can have access to tranexamic acid (TXA) even if you are not in this study.

How will my privacy be protected?
The researchers will keep your identity confidential, as required by law. Your health information is protected by a federal privacy law called HIPAA. If you sign this consent form, you give permission for KUMC to use and share your health information. You can decide not to sign this form and not be part of the study.

Dr. Kyle Sweeney and members of the research team will only use and share information that is needed for the study. They will collect health information from the study activities and from your medical record. Your medical records may contain information such as name, address, phone, date of birth, social security number, or other identifiers. Others at KUMC might need to look at your research records. They include KUMC Research Institute, the Institutional Review Board or other committees and offices that review and monitor research studies.

If you sign this form, you give the study team permission to share your research information with people outside KUMC. These groups or agencies may make copies of study records for audit purposes. Some of these groups might not have to comply with the HIPAA law, but they have agreed to protect your information. These groups may include:

- Groups that process lab samples or help manage the study
- Experts who inspect the study information to see if the study is being done correctly and if it is still safe to continue
- The FDA and similar groups in foreign countries
- Other federal agencies that oversee human research (if a study audit is performed)
- Ethics committees that review the study for other locations

Your study information will be labeled with your research ID number. The KUMC study team will keep a separate list that matches your name to the research ID number. By taking these steps, there is less risk that your personal identity and information will be seen by others who shouldn't have it.

Researchers plan to use your information indefinitely unless you cancel your permission. Any research information that is put in your medical record will be kept indefinitely. You have the right to see and copy any study information that is included in your medical record.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

Will I be told about research results?

The study team will contact you to tell you about any study results that directly affect your medical care. The overall results of this study will not be shared with you directly.

How will my research information and specimens be used in the future? In the future, researchers at KUMC and at other locations might re-use the information and specimens from this study for other research. If that happens, information that could identify you will be removed first. You will not be asked if you agree to the future research that has identifiers removed.

Can I stop being in the study?
You may stop being in the study at any time. Stopping will not prevent you from getting treatment or services at KUMC

You can choose to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Kyle Sweeney. The mailing address is Dr. Kyle Sweeney, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you about you unless they need information about a side effect of TXA. They are permitted to use and share information that was gathered before they received your cancellation.

Could my participation be stopped early?
This study might be stopped, without your consent, by the investigator by the FDA. Your participation also might be stopped by the investigator if it is no longer safe for you or if you do not follow the study requirements.

Who can I talk to about the study?
Dr. Kyle Sweeney or other members of the study team should answer all your questions before you sign this form. They will also tell you if they learn anything new that might affect your decision to stay in the study. You can talk to the researchers if you have any more questions, suggestions, concerns or complaints. If you have questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the KUMC Institutional Review Board at (913) 588-1240. You may also write the Institutional Review Board at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.

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.

CONSENT
Dr. Kyle Sweeney or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily agree to be in this research study. You have read the information and had your questions answered. ***You will be given a signed copy of the consent form to keep for your records.***

_____
Print Participant's Name

_____ _____ _____
Signature of Participant Time Date

_____
Print Name of Person Explaining Consent

_____ _____ _____
Signature of Person Explaining Consent Time Date