Protocol Title: Intravenous Tranexamic Acid in Total Shoulder Arthroplasty and Reverse Total Shoulder Arthroplasty

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Title of Study: Intravenous Tranexamic Acid in Total Shoulder Arthroplasty and Reverse Total Shoulder Arthroplasty

Sponsor: Department of Orthopaedics

RUSH

Subject Information Sheet and Consent Form

Introduction

You are invited to volunteer to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate.

You do not have to take part in this study. If you agree to take part, you will be asked to sign this form. Your signature means that you have read or had this form read to you and you have had all your questions answered by the study doctor or study staff. Before you have anything done for this study, you must sign this form. A copy of this signed subject information sheet and consent form will be given to you. You will be free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who agree to be a part of a research study are called "subjects" instead of "patients".

Why are you invited to participate in this study?

You are being asked to take part in this study because you are undergoing a total shoulder replacement or reverse total shoulder replacement.

What is the purpose of this study?

The purpose of this study is to compare the use of intravenous (IV, by vein) tranexamic acid versus IV saline placebo(A matching salt solution that contains no active ingredients)in subjects undergoing total shoulder replacement and reverse total shoulder replacement. Tranexamic acid is currently approved by the Food and Drug Administration (FDA) for use in preventing bleeding during dental procedures in hemophilia (a bleeding disorder) patients, and in women with heavy menstrual bleeding. Tranexamic acid is also commonly used at different hospitals around the United States and Europe, including at Rush University Medical Center, to reduce blood loss and transfusions (administration of blood products) in trauma victims and patients undergoing knee and hip replacements. Tranexamic acid has not been studied in shoulder replacement, so the purpose of this study is to see if it reduces blood loss and transfusions in shoulder replacement patients.

How many people are expected to take part in the study?
300 subjects are expected to be enrolled in this study at Rush University Medical Center.

What will you be asked to do?
You will be asked to agree to participate in a study to determine if IV tranexamic acid is more effective than placebo at reducing blood loss following total shoulder replacement or reverse total shoulder replacement. If you agree to participate you will be randomly assigned to one of the two groups being tested (IV tranexamic acid or IV saline placebo). You have a 50/50 chance of being assigned to either group, similar to a coin toss. Your care will not differ, except for the use of a single dose of IV tranexamic acid or IV saline placebo in the operating room 10 minutes prior to your surgery.

How long will you be in the study?
You will be in the study for the time you are in the hospital during and after your surgery.

You may be removed from this study without your consent. Some possible reasons may include the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, your disease becomes worse, you are unable to take the treatment as indicated, or the study is canceled.

What are the possible risks of the study?
Tranexamic acid is routinely used every day in both primary and revision knee and hip replacement surgeries. Although it has not been studied in shoulder replacement patients, we anticipate similar effectiveness in reducing blood loss from surgery without increased risk of complications. We will be collecting information regarding blood loss during surgery. The risk of symptomatic blood loss during surgery is low and participation in this study will not impact your care during surgery. There may be a risk of gastrointestinal symptoms such as nausea, vomiting or diarrhea as well as risk of hypotension (low blood pressure), dizziness, headache, blurred vision, and skin rash. There is also a risk of a blood clot, possibly causing difficulty breathing, or swollen ankle and pain in the calf or thigh. The risk of a blood clot is higher if you are using hormonal birth control (such as birth control pills), are obese or a smoker. However, most studies in orthopedic surgery report no side effects with tranexamic acid use.

There is the potential for breach of confidentiality and/or privacy. Below is a description of the procedure for maintaining confidentiality.

Are there benefits to taking part in the study?
There may be no direct benefit to you for participating in this study.

What other options are there?
The only alternative to participating in this study is not to participate. You do not need to participate in this study to receive your shoulder replacement treatment.

What about confidentiality of your information?
Records of participation in this research study will be maintained and kept confidential as required by law.

A breach of confidentiality and/or privacy is a risk of this study. To prevent this, all collected data will be stored electronically in password-protected files to protect patient identity and information. All information will be collected and reviewed by the research team only. Data will be maintained on a password-protected computer that will be accessible only to the study team. No patient identifiers will be maintained in the database.

A description of this study will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law. This Website 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 anytime.

In order to conduct the study, the study doctor, ***Anthony Romeo, MD or Gregory Nicholson, MD*** will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is entitled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

Your identity will not be revealed on any report, publication, or at scientific meetings. All study materials are stored in secure areas and on secure password protected computers in the secure research offices.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as the cost associated with care before, during, and after your surgery will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. The study will be responsible for the cost of the tranexamic acid and IV saline placebo.

Will you be compensated or paid?

You will not receive compensation for study participation. Your participation in this research study may contribute to the development of commercial products from which the sponsor, company, or others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or

she will explain your treatment options to you or tell you where you can get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you inform emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Anthony Romeo or Gregory Nicholson, 1611 W. Harrison St. Suite 300, Chicago IL, 60612; 1-312-432-2452 or 1-312-432-2337. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE WITNESS:
I observed the signing of this consent document.

Signature of Witness	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature
Signature of the Principal Investigator	Date of Signature