CAROLINAS HEALTHCARE SYSTEM
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

The Use of Tranexamic Acid to Reduce Blood Loss in Acetabular Surgery

INTRODUCTION

Dr. Karunakar and his associates in the Department of Orthopaedic Surgery at Carolinas HealthCare System (CHS) are asking you to participate in a research study investigating the role of tranexamic acid on blood loss during surgery. You are being asked to take part because you have had an acetabulum fracture (a break to socket of the hip joint). The purpose of this study is to determine the effect of tranexamic acid on blood loss and outcome after surgery to the acetabulum. We will also analyze whether the use of tranexamic acid is cost effective relative to other blood loss management strategies.

You will be one of approximately 50 people involved in this research project at CHS, and your participation will last for one month.

Tranexamic acid is Food and Drug Administration approved for controlling bleeding in patients with hemophilia (a genetic bleeding disorder in which it takes a long time for the blood to clot) undergoing dental surgery but not for patients undergoing acetabulum surgery. It has been used for reducing bleeding and the need for transfusion(the transfer of whole blood or blood products from one individual to another) in numerous studies of patients undergoing spine and arthroplasty (joint replacement) surgery. It has also been studied in trauma patients to reduce blood loss and reduce death.

HOW THE STUDY WORKS

If you agree to be in the study, you would be randomized to one of two treatments. Being randomized means that you are put in a group by a chance process, like flipping a coin. You won't know what group you are in and neither will your doctor. We are using this method because it is not clear at the present time whether the proposed treatment is better than the current standard of care. Your chance of receiving either treatment is one in two.

- Group 1: Tranexamic acid
- Group 2: Placebo (inactive medicine)

Although you and your doctor will not know which treatment you are receiving, this information can be determined in the event of an emergency.

After you sign this informed consent and agree to be part of the study, the following things will happen:

- You will be assigned to one of two groups.

  - If you are randomized to the treatment group, you will be administered a 10mg/kg dose of tranexamic acid within 30 minutes of surgery followed by a 10mg/kg infusion through an IV(through your vein) over a 4 hour period.
  - If you are randomized to the control group (placebo), you will be administered saline (salt water) through an IV (through your vein) during surgery as part of your care for your fracture.
  - You may also receive blood transfusion if needed as part of the care of your injury.
- You will be asked about your demographic and medical history.
- We will also record information about your surgery, such as blood transfusions and loss.
- We will follow you 30 days after your surgery to document any complications (infections, clots in the blood vessels, stroke or heart attacks) you may experience.
- We will also document how many days you spend in the hospital.

As part of your care at Carolina Medical Center, your surgeon will ask you to sign a separate consent form for your surgery.

RISKS

The study has several risks. First, you may be in the placebo (inactive medicine) group and will not receive the active medication. Second, it is possible that you will get the new treatment but do less well than you would do if you had not received it. Third, because the treatment is new for acetabulum fractures, we may not yet know all the side effects: something unexpected could happen. The known side effects are:

Rare but serious

- As with all medications, side effects may include allergic reaction. Allergic reactions may range from minor itching or rash to major reactions which can result in death.

Complications reported by patients, but not proven to be caused by this drug

- Blood clot in vein
- Pulmonary embolus, a blood clot travelling to the lung

If you have problems that might be related to the (drug) (device) (treatment), your doctor may "break the code" to find out which group you are in.

EXCLUSION CRITERIA

- You are under the age of 18 and undergoing acetabulum surgery
- You have color-blindness (color vision changes used to assess toxicity)
- You have a subarachnoid hemorrhage, bleeding between the brain and the thin tissue that covers it.
- You have an active intravascular coagulation (a bleeding disorder).

- You have a previous history of venous thromboembolism (blood clot in the vein) or with a history of hypercoaguable (excessive clotting) conditions (meaning, Factor V Leiden, antiphospholipid antibody).
- Prisoners
- Pregnancy

BENEFITS
This study may or may not improve your condition. The information gained from your case may benefit others with your condition.

ALTERNATIVE PROCEDURE/TREATMENT
If you choose not to participate in the study your healthcare will not be affected. Your doctor will discuss treatment options with you and prescribe the regimen that you agree upon.

ADDITIONAL COST
There will be no additional cost to you as a result of participating in this research.

COMPENSATION
In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You do not waive any legal rights by signing this consent form.

WITHDRAWAL
Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, that will not in any way harm your relations with your doctors or with Carolinas HealthCare System. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Carolinas HealthCare System.

We will tell you about new medical findings that may affect your willingness to continue in the study.

CONFIDENTIALITY:
The records of this study will be kept private. In any sort of report we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Carolinas HealthCare System, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

A description of this clinical trial will be available on 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.

AUTHORIZATION:
If you wish to take part in this clinical study, you will be asked to sign this consent form. It allows the study investigator to collect, process any relevant personal health information collected from you during the study. These are activities routinely carried out during all clinical studies.

You have been told that personal information about you (including sensitive personal health information, such as your medical history and your racial/ethnic origin if relevant to the study) will be reviewed, collected on a computer database, stored in electronic or manual files, audited, and/or otherwise processed by:

- the clinical study investigator, Dr. Karunakar, and research staff,
- regulatory or other governmental authorities of the United States and other countries,
- other persons authorized by the study sponsor,
- Carolinas HealthCare System employees,
- other persons or agencies as required by law or allowed by federal regulations.

You have been told that your personal data are being collected and processed to:

- check your suitability to take part in the study,
- monitor your treatment with the study medication.

You have been told that your personal information may be processed within the U.S. or elsewhere in the world or transferred to or from the U.S. for review, processing and/or storage by an associated company or a carefully selected third-party organization. By signing this document, you explicitly consent to the transfer of your personal information, including sensitive personal information, collected during this clinical study, for review, processing and/or storage. Your personal health information may be further shared by the groups above. If shared by them, the information will no longer be covered by the Privacy Rule. However, the groups are committed to keeping your personal health confidential.

You may refuse this authorization to transfer your personal information. If you choose not to agree to this authorization, you might be ineligible to participate in the study. If you decide not to sign this authorization, that will not harm your relations with your doctors or with Carolinas HealthCare System.

You have the right to inspect your medical record at any time. Your research record may be unavailable until the conclusion of the study. At that point, it will be available. Please speak with the study doctor if you desire to access your record.

You have been told whenever your personal information is processed; it will be kept confidential and secure, to the best of our ability. It will be used only for the purpose for which it was collected.

This Authorization does not have an expiration date. You have been told that according to the guidelines for good clinical practice, the study investigator and sponsor will keep your personal information for at least 6 years. If you do not withdraw this Authorization in writing, it will remain in effect indefinitely. If you wish to revoke authorization to use your personal information, you will notify the study doctor, Madhav Karunakar, 1025 Morehead Medical Center Drive Charlotte NC 28204 at 704-355-4638, in writing. Some of the data obtained from your record prior to your revocation may still be used if considered necessary for the study.

FINANCIAL INTEREST OF INVESTIGATOR

The investigators taking part in this study have no financial interest in any commercial entity related to the subject of this study.

QUESTIONS

The researchers doing the study at Carolinas HealthCare System are Drs. Karunakar, Bosse, Kellam, Sims, Lack, Wilson, Hsu and Seymour. You may ask them any questions you have now. If you have questions later, you may contact Dr. Karunakar at:

Department of Orthopaedic Surgery
Carolinas Medical Center
1000 Blythe Boulevard
Charlotte, NC 28203
Telephone 704-355-4638

The Institutional Review Board is a group of people who review the research to protect your rights. If you have questions about the conduct of this study or about your rights as a research subject, you may call the chairperson of the Institutional Review Board of Carolinas HealthCare System for information regarding patients' rights in a research study. You can obtain the name and number of this person by calling (704) 355-3158.

CONSENT

I have read the above information. I have asked any questions I had, and those questions have been answered. I agree to be in this study and authorize the use of my personal health information. Dr. Karunakar will give me a copy of this form.

_____	_____	_____
Patient [representative] Print Name	Date	Time
_____	_____	_____
Patient [representative] Signature	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time
_____	_____	_____
Investigator Signature	Date	Time

Identity of representative:
___Next of Kin
___Parent/Guardian
___Healthcare Power of Attorney