The Effect of Intravenous EACA on Blood Loss and Transfusion Requirements After Bilateral VRO

Protocol and Analysis Plan

NCT # NCT02257580

12/9/2014

HOSPITAL FOR SPECIAL SURGERY
535 East 70th Street
New York, NY 10021

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: THE EFFECT OF INTRAVENOUS ε-AMINOCAPROIC ACID ON BLOOD LOSS AND TRANSFUSION REQUIREMENTS AFTER BILATERAL VARUS ROTATIONAL OSTEOTOMY (VRO): A PROSPECTIVE, DOUBLE-BLINDED, RANDOMIZED CONTROLLED TRIAL

PROTOCOL NO.:

SPONSOR: NONE

INVESTIGATOR: DAVID M. SCHER, MD

SITE(S): HOSPITAL FOR SPECIAL SURGERY

STUDY-RELATED PHONE NUMBER(S):

DR. DAVID SCHER	212-606-1253
DR. EMILY DODWELL	212-606-1451
DR. ISHAAN SWARUP	212-606-1466

IRB #: 2014-303

"You" may refer to you or your child.

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS). You are being asked to participate in this study because you are to undergo bilateral varus rotational osteotomy (VRO).

You will still be responsible for the cost of your medical care just as you would be if you were not part of this study. For example, any co-pays, deductibles, and co-insurance associated with your medical care.

This document provides you with information about this study. After reading this document, any questions you may have will be answered. You may take home a copy of this document to consider or discuss with family and friends before making your decision.

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.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

1. WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine the effect of a drug, ε-aminocaproic acid (EACA), on the blood loss and the need for blood transfusion after bilateral varus rotational osteotomy that you are scheduled to undergo. Your overall participation will continue over the course of 6 weeks after your surgery.

Varus rotational osteotomy (VRO) is an elective surgery for the hip joint, typically for the treatment of femoral deformity in young patients. During the surgery, the femur bone is re-oriented and possibly shortened in order to improve function and decrease pain. In addition to bilateral VRO, associated soft tissue and bony procedures are often required to achieve the ultimate goal of maintaining a level pelvis, a balanced spine, and mobile, pain-free hips. Given the extent of surgery, there is a potential for increased blood loss, which may require a blood transfusion.

The risk of excessive blood loss and blood transfusion in young patients after elective surgery can be reduced with certain interventions, such as medications. EACA is generally regarded as a safe medication that can be given intravenously (i.e., into a vein in your arm) during surgery to reduce surgical blood loss and the need for blood transfusion after surgery. EACA is a medication that works to decrease surgical bleeding by improving the body's ability to stop bleeding. Many studies have shown that EACA safely reduces bleeding and the need for transfusion in patients undergoing total joint replacement surgery (e.g., total hip replacement and total knee replacement) and spine surgery. However, no one has studied the effects of this medication in patients undergoing bilateral VRO. As a result, this drug is being used in an off-label manner, since it has not been previously studied in patients undergoing bilateral VRO. However, we believe that EACA may reduce blood loss during and after VRO, and thus, reduce the need for blood transfusion in patients undergoing this procedure.

A total of 30 patients will be enrolled in this study. Patients will be divided into two groups. One group will receive intravenous EACA, and the other group will receive intravenous normal saline during surgery. Normal saline is an inactive substance. In this study it serves as a "placebo" or a pretend treatment that is compared in this trial to EACA in order to test if the drug has a real effect.

Apart for the administration of this medication, patients in both groups will receive the same care.

2. WHAT WILL YOUR PARTICIPATION REQUIRE?

If you decide to be in this study, the following routine and/or experimental procedures will be performed:

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

Study Visit #	Medication Administration	Randomization	Surgery	Physical Exam	Blood draw
1) Preoperative office visit		X		SOC	SOC
2) Hospital admission	SOC		SOC	SOC	SOC
3) 6-week post-op office visit				SOC	

X= Research procedures
SOC= Standard of care (care you would receive if you were not participating in this study)

This study will select your treatment by chance. You will be assigned at random to one of two study groups. The randomization process is comparable to (or similar to) the flip of a coin. One group will receive intravenous ε-aminocaproic acid (EACA), and the other group will receive intravenous normal saline during surgery. Normal saline is an inactive substance. In this study it serves as a "placebo" or a pretend treatment that is compared in this trial with EACA in order to test if the drug has a real effect. It is not known if any treatment you receive will benefit you. It is hoped the knowledge gained will benefit others in the future.

You and/or your insurance will be responsible for any costs of all procedures performed that are standard of care, that is, care that you would receive even if you were not in this study.

A total of 30 subjects will participate in this study at HSS.

Your participation will involve a total of two study visits and your admission to the hospital, when you undergo your surgery. Most visits are expected to last less than 30 minutes:

1. The first study visit will be your preoperative appointment. Your surgeon will perform all of his or her routine preoperative tests and exams during this visit. These are not part of the study. You will be randomly assigned to one of the study groups. You will not be told to which study group you are assigned. The total time for this visit should be approximately 30 minutes.
2. The second study visit will be your hospitalization, when your surgery is performed, the study medications will be given, and routine postoperative blood draws will be performed. During these blood draws, approximately 2 teaspoons of blood will be taken. No additional time will be required for your participation in the study. After surgery, you will receive the same care in the hospital as any other patient having undergone bilateral varus rotational osteotomy.
3. The third study visit will be your 6-week appointment after surgery. As a study participant, your surgeon will perform a routine physical exam. The total time for this visit should be approximately 30 minutes.

3. WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN FROM BEING IN THE STUDY? WHAT RISKS ARE KNOWN ABOUT THE STUDY DRUG/STUDY DEVICE?

The known effects, discomforts and foreseeable risks of physical, psychological, sociological, or other harm which you may reasonably expect to occur from being in this study are:

There is concern that a drug like ε-aminocaproic acid (EACA) which prevents bleeding may also cause a risk of blood clotting disorders, such as deep vein thrombosis (a blood clot in the leg or arm), pulmonary embolism (a blood clot in the lung), transient ischemic attack (sudden loss of blood flow to the brain that lasts for a few minutes to an hour but has no lasting effect), and stroke. However, multiple studies have shown that there is not an apparent increase in the risk of these events in patients who have received EACA. Since there is a theoretical risk of these events, the investigators will assemble an independent monitoring group of health care professionals at the Hospital for Special Surgery, who are not otherwise involved in the study. The group, called a "Data Safety Monitoring Board", will monitor patient safety throughout the trial. Also, the investigators will not permit patients to participate in the study if they have any of the following conditions and/or risk factors:

- History of allergy to ε-aminocaproic acid
- History of thromboembolic event (e.g., deep vein thrombosis, pulmonary embolism, transient ischemic attack, and stroke)
- History or evidence of kidney function problems
- History of leukemia (blood cancer)
- History of bleeding disorder or evidence of bleeding disorder on preoperative blood tests
- Use of hormone replacement therapy or hormonal contraceptive agent (i.e., birth control) within 7 days prior to surgery
- Currently pregnant
- Currently breastfeeding

As part of your surgery and post-operative care in the hospital, you may need to receive transfusions of blood products. These products come from healthy volunteers from the general population who choose to donate blood for the use of patients. Blood donors and blood products are carefully screened and tested to minimize the risk of transmitting any infectious disease or problems, but it is impossible to eliminate all risks. However, not receiving a transfusion when needed can carry a great risk of serious injury or death. Alternatives to transfusion, such as hemoglobin substitutes, are not in general use at this time.

Whether or not you are involved in this study, you will receive routine blood draws after your surgery to ensure your safety following the procedure. Blood draws or "venipuncture" involves taking blood from a vein in your hand or arm by needle stick. The risks associated with drawing blood from your arm or hand include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

If you are placed in the "placebo" group, you will receive the same care as the patients in the EACA group. There are no risks associated with being placed in the "placebo" group.

Participation in this research involves the potential risk of a breach of confidentiality to your stored health information. HSS tries to minimize those risks by (i) removing some direct identifiers from stored information (i.e., names and medical record numbers); (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

There may be risks or side effects that are unknown at this time. If we learn about new risks that may affect your willingness to continue your participation, we will make you aware of them and you will be asked to re-consent to continue your participate in the study.

4. WHAT BENEFIT CAN YOU EXPECT?

This study includes an investigational medication which may not give you immediate benefit or any benefit. The knowledge gained may benefit others in the future.

5. COST

Those research procedures listed in Section 2 will be covered by the study and will not be your financial responsibility.

As indicated in Section 2, those costs which are considered Standard of Care for your treatment here at Hospital for Special Surgery will be your/or your insurance's responsibility. You will be responsible for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be for any costs billed to your health insurance outside of this study. You will also be financially responsible for any medical care costs not covered by your health insurance.

HSS is committed to providing financial assistance when financially warranted and consistent with its resources, regardless of age, gender, religion, race or sexual orientation. So if you do not have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. Eligibility determinations are made on a case-by-case basis in accordance with HSS's financial assistance policy. You will be responsible for any costs not covered by financial assistance, which could be all of the costs (if HSS determines that you are not eligible for financial assistance) or some of the costs (if financial assistance awarded by HSS does not cover all of the costs). **For more information about the Financial Assistance Program or to request a** Financial Assistance Application **call (212) 606-1505 to speak with a Financial Assistance Counselor or you can** visit the following site: http://www.hss.edu/patient-financial-assistance-notice.asp.

6. PREGNANCY <AS APPLICABLE>

Due to inherent risks, HSS policy prevents pregnant women from receiving the type of intervention needed to qualify for this research study. Therefore, women who are pregnant or nursing a child may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant during the next year. If you suspect that you have become pregnant during this study, you must notify the study doctor immediately.

7. PAYMENT FOR PARTICIPATION

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

8. COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY

There are no plans to compensate you for the use of the findings of this study, or any of the information or biologic materials (such as blood or tissue) collected from you during the study, even if they are used to develop or make a commercial product (such as a drug, device, biologic substance, or test).

9. ALTERNATIVES: WHAT OTHER TREATMENT IS AVAILABLE IF YOU DON'T WANT TO BE IN THE STUDY?

You do not have to participate in this study to receive treatment for your condition. You will be eligible to undergo your scheduled bilateral varus rotational osteotomy even if you do not agree to participate in this study.

You should ask the study doctor about other alternative treatments that may be available for your condition.

10. WHO WILL BE ABLE TO SEE YOUR RECORDS AND PERSONAL INFORMATION AND KNOW THAT YOU ARE IN THE STUDY?

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to see your information and why they will be able to see it. The study doctor must obtain your authorization (permission) to use or give out any health information that might identify you.

<u>What information may be used or given to others</u>?

If you choose to be in the study, the study doctor will get personal information about you. The information might identify you. The study doctor may also get information about your health including:

- Medical and research records
- Records about phone calls
- Records about your study visits
- Records of physical exams
- Laboratory, x-ray, and other test results
- Questionnaires
- Records about any study device you received

<u>Who may use, disclose, or receive my information</u>?

The following person(s) class(es) of persons, and/or organization(s) may use, disclose, or receive my information:

- The Principal Investigator and other Investigators for this study, including your study doctor.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

- The research coordinator, research nurses, and other members of the HSS research team working on this study.
- Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital, and Memorial Sloan-Kettering Cancer Center. This includes the research staff and medical staff at each institution.
- The Patient Advocate or Research Ombudsman at these institutions.
- Staff members of HSS responsible for administering clinical trials and other research activities
- Any laboratories and other individuals and organizations that analyze your health information for this study.
- Any health care provider that you have used in the past or may use up to the time this study ends.
- The United States Food and Drug Administration (FDA), the federal Office for Human Research Protections (OHRP), any federal agency that provides support for this study, and any federal, state, or local agency responsible for overseeing HSS, the study doctor, or any other member of the HSS research team involved in this study.
- The members and staff of the affiliated Institutional Review Boards (IRBs) at HSS, New York-Presbyterian Hospital, and Memorial Sloan-Kettering Cancer Center. An IRB is a committee of health care providers, community representatives, and others that initially approves and periodically reviews biomedical and behavioral research that involves human subjects in order to protect the rights, safety and welfare of study participants.
- Data Safety Monitoring Boards and others authorized to monitor the conduct of this study for safety or quality assurance, for example a Clinical Events Committee.

Why will this information be used and/or given to others?

Your health information may be given to others to carry out this study. The sponsor will analyze and evaluate the results of this study. People working for the sponsor also visit HSS and other research sites to make sure this study is being done correctly.

Your health information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can get approval to market new products resulting from this study. Your information may also be used to meet the reporting requirements of governmental agencies.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

What if I decide not to give permission to use and give out my health information?

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you cannot be in this study.

May I review or copy the information obtained from me or created about me?

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

You have the right, in accordance with Hospital policy and applicable law, to review and copy your health information that is created or obtained in the course of this study. However, if you decide to be in this study and sign this informed consent form, you will not be able to look at or copy your information until after the study is completed if doing so would impact the validity of the study (for example, if the study is "blinded" so that during the study you will not know what treatment or other intervention you are receiving).

May I revoke (take back) my permission?

Yes. Your permission will never expire unless you revoke it. To revoke your permission, you must write to the study doctor at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

You may revoke your permission to use and disclose your health information at any time. If you revoke your permission, you cannot continue to participate in this study.

After you revoke your permission, no new health information that might identify you will be gathered. Information that has already been gathered may still be used and given to others. This would be done if the information is needed for this study to be reliable.

Is my health information protected after it has been given to others?

Some persons who receive your health information may not be required to protect it, and they may share your information with others without your permission, if permitted by laws governing them. Therefore, there is a risk that your information will be released to others without your permission.

11. CONFLICT OF INTEREST NOTIFICATION

HSS is concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS significant financial interests (such as stock ownership, royalty payments, and consulting agreements) and relationships (such as membership on a scientific advisory board) that are related to their research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her studies, HSS's Conflict of Interest Committee for Research reviews the information to evaluate the risk that the interest or relationship might influence how the investigator conducts the study or interprets the results of the study. HSS may also take steps to minimize that risk.

☒ The Conflict of Interest Committee for Research has determined that there are no conflicts of interest associated with this study.

☐ The Conflict of Interest Committee for Research has determined that there is a potential conflict of interest associated with this study. Please read the information below carefully.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

12. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at HSS and your medical care at HSS, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and/or the sponsor may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

13. COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other HSS professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining appropriate follow-up medical treatment. However, there is no plan to routinely provide compensation for additional medical care or other costs.

Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

14. SOURCE OF FUNDING

Funding for this study will be provided by the Hospital for Special Surgery.

15. QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Dr. David Scher can be reached at 212-606-1253 during office hours and after business hours.

If you have any questions about your rights as a participant in this study or any questions about your participation that you would like to ask an institutional representative who is not part of this study, you can call the Manager of the HSS Institutional Review Board at (212) 774-7154.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact the Hospital's Office of Legal Affairs at (212) 606-1592. You may also ask the Hospital's patient advocate at (212) 774-2403, to arrange for you to have this information.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign the next page of this informed consent form. By signing the next page, you are voluntarily agreeing to be in this study at HSS.

Before signing, you should be sure of the following:

- You have read all of the information in this "Informed Consent to Participate in Research" form (or had it read to you).
- You have discussed the implications of your being in this study with your doctor, your study doctor and/or the study coordinator.
- You have had the chance to ask questions about this study.
- You received answers to your questions.
- If you did not understand any of the answers, you asked the study doctor or the study coordinator to explain them to you.
- The information given to you is based on what is now known about the study drug(s), device(s), or procedure(s). There may be other risks or complications that are not known at this time.
- You have had time to think about the information and decide whether or not to be in the study.

Please check one of the following:

☐ I AM NOT in another research study at this time.

☐ I AM in another research study at this time.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

You must be given a signed copy of this informed consent form to keep for yourself.

_____	_____	
Print Name of Participant	Signature of Participant	Date
_____	_____	
Print Name of Parent/Legal Guardian (if applicable)[1]	Signature of Parent/Legal Guardian	Date
_____	_____	
Print Name of Parent/Legal Guardian (if applicable)[2]	Signature of Parent/Legal Guardian	Date
_____	_____	
Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

_____
As an HSS representative, please sign here to indicate that you have given a signed copy of this informed consent form to the participant

NOTE TO INVESTIGATORS:

[1] The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.

[2] The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY**.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

Hospital for Special Surgery
535 East 70th Street
New York, NY 10021

Assent Form for Older Adolescent (13-18) Participation in Research Study

The Name of the Study is: THE EFFECT OF INTRAVENOUS E-AMINOCAPROIC ACID ON BLOOD LOSS AND TRANSFUSION REQUIREMENTS AFTER BILATERAL VARUS ROTATIONAL OSTEOTOMY (VRO): A PROSPECTIVE, DOUBLE-BLINDED, RANDOMIZED CONTROLLED TRIAL

The Investigator(s) is/are:

DR. DAVID SCHER	212-606-1253
DR. EMILY DODWELL	212-606-1451
DR. ISHAAN SWARUP	212-606-1466

The Sponsor of the Study is: None

HSS IRB #: 2014-303

Introduction:
You are being asked to take part in a research study. Before you decide to be a part of this research study, you need to understand the risks and benefits so that you can make an informed decision. This is known as informed consent.

Once you understand the study and the tests it requires, you will be asked to sign this Assent Form if you want to take part in the study. Your decision to take part in the study is voluntary. This means that you are free to decide if you want to take part in the study. You are also free to withdraw or stop taking part in the study at any time during the study.

The Study:
The purpose of this study is to determine the effect of a drug, ε-aminocaproic acid (EACA), on blood loss during your surgery and the need for blood transfusion after your surgery. Your overall participation will continue over the course of 6 weeks after your surgery.

Your surgery (called bilateral varus rotational osteotomy (VRO)) is an elective procedure for the hip joint, typically for the treatment of femoral deformity in young pateints. During the surgery, the surgeon changes the position of the femur and possibly shortens it in order to improve function and to decrease pain. In addition to bilateral VRO, other procedures are often required to achieve the ultimate goal of maintaining a level pelvis, a balanced spine, and mobile, pain-free hips. Since this is a long and complicated surgery, there may be increased blood loss, which could require a blood transfusion.

EACA is generally regarded as a safe medication that can be given into a vein in your arm during surgery that may reduce blood loss and the need for blood transfusion after your surgery.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

A total of 30 patients will take part in this study. Patients will be divided into two groups. One group will receive intravenous EACA, and the other group will receive an intravenous normal salt water solution (saline) during surgery. Normal saline is an inactive substance. In this study it serves as a "placebo" or a pretend treatment that is compared to EACA in order to test if the drug has a real effect. After surgery, you will receive the same care as any patient undergoing your same surgery. This includes routine blood draw from veins in your arm and/or hand.

If you are willing to take part in the study, you and your parent(s) must first have the study explained to your satisfaction and all of your questions answered. When you agree to participate in the study, you will need to sign this Assent Form, and then you and your parent(s) will also need to sign the Informed Consent Form. Copies of these forms will be given to you.

_____	_____
Print Name of Participant	Signature of Participant Date
_____	_____
Print Name(s) of Parent(s)/Legal Guardian[3]	Signature(s) of Parent(s)/Legal Guardian Date
_____	_____
Print Name(s) of Parent(s)/Legal Guardian	Signature(s) of Parent(s)/Legal Guardian Date
_____	_____
Print Name of Person Obtaining Assent	Signature of Person Obtaining Assent Date

_____

As an HSS representative, please sign here to indicate that you have given a signed copy of this informed assent form to the participant

NOTE TO INVESTIGATORS:

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY**.

[3] The signature of **one parent** is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of **both parents** is **required** when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

Hospital for Special Surgery
535 East 70th Street
New York, NY 10021

Assent Form for Young Minor (7-12) Participation in Research Study

The Name of the Study is: THE EFFECT OF INTRAVENOUS E-AMINOCAPROIC ACID ON BLOOD LOSS AND TRANSFUSION REQUIREMENTS AFTER BILATERAL VARUS ROTATIONAL OSTEOTOMY (VRO): A PROSPECTIVE, DOUBLE-BLINDED, RANDOMIZED CONTROLLED TRIAL

The Investigator(s) is/are:

DR. DAVID SCHER	212-606-1253
DR. EMILY DODWELL	212-606-1451
DR. ISHAAN SWARUP	212-606-1466

The Sponsor of the Study is: None

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

Introduction:
You are being asked to take part in a research study. Before you decide to be a part of this research study, you need to understand the risks and benefits so that you can make an informed decision. This is known as informed consent.

Once you understand the study and the tests it requires, you will be asked to sign this Assent Form if you want to take part in the study. Your decision to take part in the study is voluntary. This means that you are free to decide if you want to take part in the study. You are also free to withdraw or stop taking part in the study at any time during the study.

The Study:
The purpose of this study is to determine the effect of a drug, ε-aminocaproic acid (EACA), on blood loss during your surgery and the need for blood transfusion after your surgery. Your overall participation will continue over the course of 6 weeks after your surgery.

Your surgery (called varus rotational osteotomy (VRO)) is an elective procedure for hips, typically for treating thigh bone deformity in children. During the surgery, the surgeon changes the position of the thigh bone and possibly shortens it in order to help you move better and to lessen your pain. In addition, other procedures are often required to achieve the ultimate goal of maintaining level hips, a balanced spine, and mobile, pain-free hips. Since this is a long and complicated surgery, there may be increased blood loss, which could require a blood transfusion.

EACA is generally considered as a safe medication that can be given into a vein in your arm during surgery that may reduce blood loss and the need for blood transfusion after your surgery.

A total of 30 patients will take part in this study. Patients will be divided into two groups. One group will receive EACA, and the other group will receive a normal salt water solution (saline) during surgery. Both medications will be given into a vein in your arm during surgery. Normal saline is an inactive substance. In this study it serves as a "placebo" or a pretend treatment that is compared to EACA in order to test if the drug has a real effect. After surgery, you will receive the same care as any patient undergoing your same surgery. This includes routine blood draw from veins in your arm and/or hand.

If you are willing to take part in the study, you and your parent(s) must first have the study explained to your satisfaction and all of your questions answered. When you agree to participate in the study, you will need to sign this Assent Form, and then you and your parent(s) will also need to sign the Informed Consent Form. Copies of these forms will be given to you.

_____	_____
Print Name of Participant	Signature of Participant Date
_____	_____
Print Name(s) of Parent(s)/Legal Guardian[4]	Signature(s) of Parent(s)/Legal Guardian Date

[4] The signature of **one parent** is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of **both parents** is **required** when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»

Print Name(s) of Parent(s)/Legal Guardian	Signature(s) of Parent(s)/Legal Guardian Date
Print Name of Person Obtaining Assent	Signature of Person Obtaining Assent Date

As an HSS representative, please sign here to indicate that you have given a signed copy of this informed assent form to the participant

NOTE TO INVESTIGATORS:

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY**.

IRB Administrative Use Only

«Approval»
«ApprovalDate» Thru «ExpirationDate»