UNIVERSITY OF CALIFORNIA LOS ANGELES
CONSENT TO PARTICIPATE IN RESEARCH

STUDY TITLE: ACCESS PTS: Accelerated Thrombolysis for Post-Thrombotic Syndrome Using the EKOS System

LAY TITLE: Accelerated breakdown of a blood clot located in the lower extremity using the EKOS System

STUDY SPONSOR: EKOS Corporation

PROTOCOL NUMBER: EKOS – 11

PRINCIPAL INVESTIGATOR: Stephen Kee, MD.

INTRODUCTION
Dr. Stephen Kee and Dr. John Moriarty and associates from the Department of Radiology, at the University of California, Los Angeles are conducting a research study.

The researchers will explain this study to you. Research studies are voluntary and include only people who choose to take part. Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with friends and family.
- You can also discuss it with your health care doctor or request a second opinion.
- If you have any questions, you can ask the researchers for more information before deciding to participate.

The research team is asking you to be in this study because you may qualify to participate in this study.

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to evaluate how much clot in your vein can be dissolved using the EKOS system with Activase which is a thrombolytic drug, a drug that dissolves clots, how much blood flow can be restored in your leg and whether your current symptoms improve after treatment.

This study is being sponsored by EKOS Corporation

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
There will be approximately 200 evaluable subjects in locations around the United States who will participate in this study. (An evaluable subject needs to have certain x-ray and Doppler ultrasound recordings before and after treatment to document the results for the study.) All subjects will be treated with a thrombolytic drug and the EKOS system. Up to 15 people will take part in this study at UCLA.
MATERIALS:
The EKOS system is made of the same materials routinely used in medical catheters and other standard medical devices. The drug used to dissolve the clot is routinely used in the hospital for this purpose.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?
Before you begin the study:
Before you begin the study, you will need to be evaluated by your doctor to determine if you are eligible to participate in this research study. This evaluation will include documenting your medical history, having a physical examination, laboratory tests using approximately 1½ tablespoons of blood to assess your blood count and blood clotting factors, a non-invasive test using Doppler ultrasound to evaluate the blood flow in your vein, and a venogram which is a special x-ray of the veins in your leg to locate the blood clot(s) and narrowing(s) in your vein. For the venogram, a liquid that can be seen on x-ray pictures (dye) will be injected into your leg vein through a catheter (small tube) so the doctor can see how the blood flows through your veins. These tests will be conducted whether or not you are participating in this clinical research study.

Beginning 48 hours prior to the date of your scheduled EKOS procedure you will be given a prescription for enoxaparin medication. This medication is a self-administered subcutaneous injection and is to be given twice daily in the abdomen.

EKOS Procedure: At the beginning of the venogram procedure, you will receive a local anesthetic to numb the area where a catheter (small tube) will be inserted into your leg vein and dye will be injected while x-ray pictures are taken. The EKOS catheter will then be placed in the blood clot inside the blood vessel and the clot dissolving drug (thrombolytic drug) will be released into the clot. The EKOS system will be turned on to deliver ultrasound energy inside the vein. The drug infusion and ultrasound treatment will continue until the blood clot is dissolved, at least overnight but perhaps as long as 48 hours. You may have multiple venograms over the treatment time to determine if the blood clot has dissolved. These venograms will use the same catheter that is already in your vein. Once the blood clot is dissolved, your doctor may determine that additional treatment is needed to repair the narrowing of the vessel. All these procedures are standard of care, including the use of the EKOS system, and none are experimental.

After the EKOS Procedure:
You will be asked to return to the clinic at 1 month, 3 months, 6 months and 12 months after your procedure and have a physical examination, a non-invasive Doppler ultrasound examination of your leg and pelvis, and complete several questionnaires about your symptoms. In addition to these follow up visits and tests, you will also be required to continue with the self-administration of the enoxaparin injections for 30 to 90 days following the procedure.
WHAT KINDS OF RISKS OR DISCOMFORTS COULD I EXPECT?

The risks that are associated with use of the EKOS EkoSonic Infusion System are expected to be the same as the risks associated with any catheter directed infusion procedure of thrombolytic drugs. These risks may include but are not limited to:

- Pain and tenderness - Common
- Bleeding that may require a transfusion - Less common
- Hematoma (a mass of clotted blood in the body) - Less common
- Blood infection/whole body inflammation - Less common
- Distal embolization (obstruction of a blood vessel away from the original obstruction) - Less common
- Thromboembolic episode (obstruction of a blood clot causing blockage) - Less common
- Formation of a clot in the blood that either block, or partially blocks a blood vessel - Less common
- Adverse drug reaction - Less common
- Abnormal connection between an artery and a vein - Rare
- Brief tightening of a blood vessel that can block blood supply to the heart - Rare
- Intracranial hemorrhage (bleed in the brain) - Rare
- Intimal disruption (rupture of plaque in the inner lining of a vessel) - Rare
- Vessel perforation or rupture (torn vessel) - Rare

The main risk associated with the thrombolytic drug you will receive (Activase) is bleeding. The bleeding may be minor such as bruising, or more severe such as a large bruise (hematoma) around the site where the catheter is inserted. A very rare, but possible complication is intracranial hemorrhage (bleeding in the brain – a serious complication that can lead to severe disability or death.

The reasonably foreseeable risks for thrombolysis procedures are pain, reaction to anesthesia and complications related to any preexisting diseases. Your doctor will explain all associated risks of this treatment. There may also be risks that are unforeseeable.

ARE THERE ANY BENEFITS IF I PARTICIPATE?

Possible benefits to me:
There will be no direct benefit to you from participating in this study.

Possible benefits to others or society:
This study will help the researchers learn more about dissolving blood clots using thrombolytic drugs and ultrasound. Hopefully this information will help in the treatment of future patients with Deep Vein Thrombosis (DVT) like yours.
WHAT OTHER CHOICES DO I HAVE IF I DON'T WANT TO PARTICIPATE?

If you decide not to take part in this study, or if you withdraw from this study before it is completed, the following alternative procedures or courses of treatment are available: balloon angioplasty which is a procedure to restore blood flow through the artery; stent placement which is a small, expandable tube permanently inserted into the artery to keep the artery open; or breaking up of the clot by use of other types of catheters. All of the treatment options will be explained to you by your treating physician.

CAN THE RESEARCHERS REMOVE ME FROM THIS STUDY?

The researchers may end your participation in this study for a number of reasons, such as if your safety and welfare are at risk, if you do not follow instructions or if you miss scheduled visits. The researchers or the study sponsor might also decide to stop the study at any time.

Your participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study without penalty or loss of benefits to which you are otherwise entitled. Your medical care and relationship with your doctor will not be affected by your decisions concerning this study. Any new information from the study that could affect your decision to continue will be provided to you. If you decide to participate, you are free to discontinue at any time.

The data collected about you up to the point of withdrawal will remain part of the study and may not be removed from the study database.

HOW WILL INFORMATION ABOUT ME AND MY PARTICIPATION BE KEPT CONFIDENTIAL?

Efforts will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. Your personal information may be disclosed for purposes related to the study, or if required or allowed by law. By law, you have certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it.

Information collected about you during this study becomes part of the research record for this study if you agree to participate. This information may include the following:
- Your name, address, telephone number, Health Plan Number, and other details about you;
- Information obtained from procedures used to find out whether you are eligible to take part in this study. This may include physical examinations, blood and other laboratory tests, x-ray and other procedures or tests, and any other information that you may release to us, including information about your health history;
• Information obtained in the course of the study including information about your response to any study treatments you receive, information related to study visits and phone calls, physical examinations, blood and other laboratory tests, x-ray and other procedures or tests, and other medical information relating to your participation in this study.

In addition, your regular medical records become part of the research record for this study if you agree to participate. The information collected about you will be used for the purposes of conducting this study as described in this consent form.

If you agree to participate in this study and you sign this consent form, you are also agreeing to allow the research team to share your information with any or all of the following:
• Investigators and other staff listed on this form
• Doctors and other healthcare providers taking part in this study
• Your health insurance company
• EKOS Corporation: the sponsor of this study
• the U.S. Food and Drug Administration (FDA)
• the U.S. Department of Health and Human Services (DHHS) agencies

The results of the research study, including information from your medical records, may be presented at meetings or in publications, but you will not be identified by name and your identity will not be disclosed.
You do not have to agree to allow these groups to look at your information, but if you do not, you may not participate in this study.

**How long will information from the study will be kept:**
All source documents, records and reports related to data provided to this study will be retained in accordance with applicable federal guidelines for at least three (3) years following the closure of the study.

**ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?**
The study sponsor will pay for the cost of the pelvic ultrasound (US) that is required to be completed for the study at every study visit.

You or your insurer will be billed for the costs of any standard medical care you receive during your participation in the study and you will be responsible for any associated co-payments and deductibles. There is a possibility that your medical insurance company may not cover these costs because you are in a research study. If this happens you might have unexpected expenses from being in this study, such as the costs associated with treating side effects. Financial counseling and itemized cost estimates are available upon request.

The EKOS infusion catheter, the enoxaparin medication that you will self-administer twice daily beginning 48 hours prior to the EKOS procedure and 30 to 90 days following
the EKOS procedure and all tests performed as a part of this research study are considered part of your standard of care and will be charged to you or a third party payer.

WILL I BE PAID FOR MY PARTICIPATION?
You will not be paid for your participation in this research study.

WHO CAN I CONTACT IF I HAVE QUESTIONS ABOUT THIS STUDY?
The Research Team:
You may contact Dr. Stephen Kee at (310) 267-8768 or Dr. John Moriarty at (310) 825-0958 with any questions or concerns about the research or your participation in this study. You can also call the UCLA Page Operator at (310) 825-6301 to reach these physicians 24 hours a day, 7 days week.

UCLA Office of the Human Research Protection Program (OHRPP):
If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UCLA OHRPP by phone: (310) 825-5344; by email: mirb@research.ucla.edu or U.S. mail: UCLA OHRPP, 11000 Kinross Ave., Suite 211, Box 951694, Los Angeles, CA 90095-1694.

Public Information about this Study:
ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial 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 website will include a summary of the results. You can search this website at any time.

WHAT HAPPENS IF I BELIEVE I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?
It is important that you promptly tell the researchers if you believe that you have been injured because of taking part in this study. You can tell the researcher in person or call him/her at the number(s) listed above.

If you are injured as a result of being in this study, UCLA will provide the necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor EKOS Corporation, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about this, you may call the UCLA Office of the Human Research Protection Program at 310-825-5344 or send an email to mirb@research.ucla.edu.
WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?
Taking part in this study is your choice. You can choose whether or not you want to participate. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.
- You have a right to have all of your questions answered before deciding whether to take part.
- Your decision will not affect the medical care you receive from UCLA.
- If you decide to take part, you can leave the study at anytime.
- If you decide to stop being in this study you should notify the research team right away. The researchers may ask you to complete some procedures in order to protect your safety.
- If you decide not to take part, you can still get medical care from UCLA.

HOW DO I INDICATE MY AGREEMENT TO PARTICIPATE?
If you agree to participate in this study you should sign and date below. You have been given a copy of this consent form and the Research Participant’s Bill of Rights to keep. You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

SIGNATURE OF THE PARTICIPANT

____________________________________
Name of Participant

____________________________________  _____________
Signature of Participant                  Date

SIGNATURE OF PERSON OBTAINING CONSENT

____________________________________  ________________
Name of Person Obtaining Consent            Contact Number

____________________________________  _____________
Signature of Person Obtaining Consent      Date