Prospective Randomized Evaluation of the Denali and Option Inferior Vena Cava Filters

ODEN Trial: Option vs. Denali IVC Filters

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Patient Name:_____

DOB: ___ / ___ / _____

UCSF MR#: _____

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

CHR# 14-13307 : Prospective Randomized Evaluation of the Denali and Option Inferior Vena Cava Filters

Dr. Maureen Kohi and her colleagues from the UCSF Department of Radiology & Biomedical Imaging (Interventional Radiology section) are asking you to participate in a research study. They will explain the study to you.

Research studies include only people who choose to take part. Please take your time to make your decision about participating. You may discuss your decision with your family and friends and with your healthcare team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because your medical team decided it is necessary for you to receive an Inferior Vena Cava (IVC) filter to prevent dangerous blood clots from going to the arteries of the lung. To reduce the risk of blood clots breaking off from veins in your legs or pelvis and traveling to your lungs, a filter will be placed into the main vein in your abdomen, the inferior vena cava (IVC). This filter is designed to trap any blood clots traveling in your venous system before they reach your lungs. Blood clots that reach your lungs may be fatal.

WHY IS THIS STUDY BEING DONE?

This study is being done to improve the care and monitoring of patients who need a filter placed in their IVC. The IVC is a large blood vessel that returns blood from the lower body to the lungs and heart. IVC filters are placed in patients who are at high risk of dangerous and potentially deadly blood clotting, known as pulmonary embolism (PE) or deep vein thrombosis (DVT).

The investigators also want to be able to detect and better understand the possible side effects and complications that two of the most commonly used IVC filters can cause. You will be selected at random to either receive the Option Elite (Rex Medical, Conshohocken, Pennsylvania)or the Denali (Cook, Bloomington, Indiana) IVC filter. Both filters are FDA-approved and have been shown to be safe and effective for use.

Early retrieval of the IVC filter is recommended when you are no longer at high risk for dangerous blood clots. Unfortunately, many patients who receive IVC filters are not carefully monitored and filters are often left in longer than necessary. Previous research has shown that the likelihood of side effects and complications from IVC filters increases over time. We seek to bring you back after a month, and determine if it is safe to remove the filter. If your doctors believe you need the IVC filter longer than a month we will postpone retrieval.

This is an investigator initiated study by Maureen Kohi MD. Neither UCSF nor any of the doctors and staff providing care during this study receives any form of compensation or funding from the manufacturers of the devices.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

One hundred fifty people will take part in this study, seventy five for each filter type.

WHAT WILL HAPPEN IF I TAKE PART IN THIS STUDY?

Before you begin the main part of the study...

You will need to have the following exams, tests or procedures, called "Screening", to find out if you can be part of the study. These Screening procedures are part of routine care before IVC filter placement and would be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- The study doctor will review the results of your most recent routine care imaging scans (CT MRI)of your abdomenor ultrasound of your lower extremities.
- The study doctor will discuss the potential risks and benefits of IVC filter placement with you.

The following Screening procedures will be done within 12 days before the IVC filter placement procedure:

- A complete physical exam
- The study doctor will ask about your medical history and how well you are able to do daily activities

During the study…

If the Screening procedures show that you can take part in the study, IVC filter placement in the study would only be offered to you if your doctor feels you are eligible and safe to receive either the Option Elite or Denali IVC filter.

If you choose to take part, the following procedures will be done during the study. Just as with Screening, all of these procedures are part of regular IVC filter placement care and would be done even if you do not join the study.

Randomization

You will be randomized to receive either the Option Elite (Rex Medical, Conshohocken, Pennsylvania)or the Denali (Cook, Bloomington, Indiana) IVC filter. "Randomized" means to be selected by chance, such as flipping a coin. There is a 50% chance of receiving either IVC filter.

Filter Placement

Placement of an IVC filter involves the insertion of a plastic tube (catheter) into a vein in either your leg or your neck. Some numbing medicine will be injected in the skin over the vein before the catheter is inserted. Intravenous medications may also be given to you to make you more comfortable and relaxed. The medicine given for pain is Fentanyl and the medicine given for sedation is Versed. This is known as moderate sedation. Once the catheter has been placed into the vein, it will be advanced through the blood vessels and into the IVC. During this time, x-ray

contrast material (x-ray dye) will be injected through the catheter and x-ray pictures taken. You may be asked to hold your breath for several seconds as these pictures are taken. During the injection of x-ray contrast material, you may experience a warm feeling or a strange taste in your mouth. Both of these sensations are temporary and will go away soon. A series of x-ray pictures will be obtained of the IVC. This is done to ensure that the size of the IVC is within the recommended range for filter placement. Once the catheter is placed into the IVC, the filter will be inserted through the catheter. During the placement procedure, positioning of the filter will be monitored with x-ray pictures. At the completion of the procedure the catheter will be removed and pressure will be applied to the insertion site until the bleeding has stopped. To help prevent bleeding, it will be very important for you to lie flat in bed without moving your leg for up to 1 hour.The doctor performing the procedure will be asked to complete a short questionnaire after IVC filter placement regarding the ease of filter placement.

Follow-Up

After the IVC filter placement procedure you will be closely followed by the interventional radiology doctors.

Per standard of care measures after IVC filter placement you will be monitored in the hospital for up to 1 hour after the procedure. If you are in stable condition and sedation has resolved you will return home the same day or be sent back to your hospital room

You will be telephoned and asked to return to the hospital one month after IVC filter placement if medically stable and your other doctors agree that IVC filter removal is recommended.If you are not medically stable or still at high risk for blood clots, we will attempt to schedule a follow up at every 1 month intervals. At this visit you will receive the following routine tests per standard of care after IVC filter placement:

- A physical exam
- The study doctor will ask about your medical history and how well you are able to do daily activities, and if you are experiencing any possible symptoms related to the IVC filter placement
- IVC filter retrieval under moderate sedation. This procedure is very similar in nature to the filter placement procedure. The IVC filter is removed via a similar process to the way in which it was placed. A rotation CT scan is performed prior to any intervention to see if the filter is intact or has penetrated through the vein. Next, a catheter will be placed in your neck (as in the case of the placement) and X-ray dye (contrast) will be injected around the filter to assure that the area beneath the filter is free of blood clots and that it is safe to proceed with removal.A catheter-based snare will be used to engage the hook at the end of the filter and the filter will then be enveloped by a removal sheath and removed from your body.

The purpose of the phone calls, clinic visits, and CT scan is to determine the soonest possible removal of the IVC filter if removal is determined to be safe.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study until your IVC filter is removed or it is determined that filter removal is not recommended by your doctor, whichever comes first. The minimum length of time would be a month. There is no expected time commitment from you outside of your regular care and treatment.

CAN I STOP BEING IN THE STUDY?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to safely stop being part of this study.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

WHAT SIDE EFFECTS OR RISKS CAN I EXPECT?

Taking part in this treatment involves some known risks, discomforts or inconvenience. There also may be risks that are unknown or unforeseeable. Your doctor has decided the benefits for you to receive an IVC filter outweigh the risks.

Possible Side Effects and Complications of IVC Filter

Likely

- Pain at insertion site
- Perforation of IVC filter into blood vessel wall
- Filter tilt

Less likely

- Infection of insertion site or blood stream
- Perforation of IVC filter into other organs or spine
- Bleeding at insertion site
- Filter migration
- Clot formation within the filter

Rare but serious

- Filter Fracture (breakage of the filter)
- Recurrent embolism (clot to your lungs or other blood vessels
- Death

IVC Filter: Risks associated with the procedure include, but are not limited to, pain or discomfort at the catheter insertion site, bleeding at the site, injury to a bloodvessel, and infection which may result in an infection of the blood stream. It is possible that the IVC will become blocked after the placement of the filter. Blockage of the IVC is a gradual process and usually does not cause any symptoms. You will develop veins around the blocked area and these veins will allow blood flow from your lower body. However, this results in the risk of a clot passing through these veins, bypassing the filter, and reaching your lungs. It is also possible that, after placement, the filter may shift in position. If your femoral vein (located in your leg) was used for the procedure, there is the possibility that the vein may become blocked. This may result in leg swelling and may require intravenous blood thinners or the use of blood clot dissolving drugs

given into the IVC. Even with an IVC filter, it is possible to experience a recurrent pulmonary embolism due to clot material passing through the small openings in the filter.

Risks of Denali vs. Option IVC filter: Currently there is little safety data on the complication and failure rates of either filter type. Both have been approved by the FDA under similar device exemptions but neither has been evaluated in depth.

Sedation: The medications used for the moderate sedation are associated with the risks of aspiration (inhaling food or liquid into your lungs) or respiratory depression.

Randomization: You will be assigned to a treatment program by chance, and the treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s) or other available treatments.

Radiation: This study involves exposure to radiation. This radiation exposure is part of routine clinical care and is not related to research. You will not receive additional radiation as a result of participating in this study. If you are pregnant or breast feeding, you SHOULD NOT participate in this study. If you have any questions regarding the use of radiation or the risks involved, please consult the physician conducting the study.

Unknown Risks: The IVC filter you receive may cause side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

For more information about risks and side effects, ask your study doctor.

Many side effects disappear shortly after the placement of the IVC filter. Other side effects may be longer lasting or permanent. Your doctor may prescribe medication to minimize these side effects.

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?

Taking part in this study may or may not make your health better. While doctors hope that close monitoring of filter placement with follow-up imaging and early filter removal may make your health better and reduce complications, there is no guarantee of that.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT TAKE PART IN THIS STUDY?

Other IVC filter types may be available and a specific filter type may be requested by you or your doctor.

- Receive the IVC filter preferred by your physician
- Receive a different IVC filter at your choice with your doctor's approval
- No filter (no treatment to help prevent dangerous clots in your lungs or blood vessels)

Ask your doctor about the risks and benefits of other IVC filter choices.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that the personal information in your medical record is kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- University of California
- The Food and Drug Administration (FDA), an agency involved in keeping research safe for people

Participation in research may involve a loss of privacy, but information about you will be handled as confidentially as possible. A medical record will be created because of your participation in this study. Your consent form and some of your research test results will be included in this record. Therefore, your other doctors may become aware of your participation. Hospital regulations require that all health care providers treat information in medical records confidentially.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

This study is performed as a standard of care (SOC) study for patients that will be receiving an IVC filter anyway as part of their normal treatment for blood clot prevention.

You and/or your health plan/insurance company will need to pay for the costs of treatment in this study. Some health plans will not pay these costs for taking part in studies. Check with your health plan/insurance company to find out what they will pay for. Taking part in this study may or may not cost you or your insurance company more than the cost of getting regular treatment.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

No, you will not be paid for taking part in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, Maureen Kohi, M.D., or one of his associates, if you feel that you have been injured because of taking part in this study. You can tell them in person or call them at 415-353-1300.

Treatment and Compensation for Injury: If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California depending on a number of factors. The University does not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Committee on Human Research at 415-476-1814.

WHAT ARE MY RIGHTS IF I TAKE PART IN THIS STUDY?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek compensation by signing this form.

WHO CAN ANSWER MY QUESTIONS?

If you have any comments or concerns about your treatment, please talk with Dr. Maureen Kohi. She can be reached by calling (415) 353-1300.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the Office of the Committee on Human Research at (415) 476-1814.

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

You have been given a copy of this Consent Form and the Experimental Subject'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.

PARTICIPATION IN RESEARCH IS VOLUNTARY

You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish toparticipate in this study, you should sign below.

Date	Signature of Subject
Date	Person Conducting Informed Consent Discussion
Date	Witness Signature (Only required if the participant is a non-English speaker)
Date	Surrogate Signature (Only required if the participant is not mentally or physically able to consent)