Comparing TR Band to Statseal in Conjunction With TR Band II

NCT04046952

VA Long Beach
IRB NUMBER: 1843
IRB APPROVAL DATE: 10/10/2019

Subject Name: _____ **Date:** _____

A PROSPECTIVE MULTICENTER RANDOMIZED STUDY COMPARING THE TIME TO HEMOSTASIS (TTH) AND SAFETY OF USING A HEMOSTASIS BAND ALONE AND IN CONJUNCTION WITH A POTASSIUM FERRATE PAD (STATSEAL ADVANCED) FOLLOWING TRANSRADIAL CATHETERIZATION.

Title of Study:

Principal Investigator: **Arnold H. Seto, MD** **VA Long Beach Healthcare System, CA**

Bill of Rights for Human Subjects in Medical Research

Any person who is requested to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10.Be given an opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

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Summary of Key Information:

You are being asked to consent to participate in a research study because your doctor has determined that you need a cardiac catheterization procedure (this is procedure where a fine tube is inserted, usually through an artery in the wrist and pushed all the way to the heart blood vessels. The tube is then used to inject a dye in the heart blood vessels so that they can be seen by the heart doctor with an Xray machine) to treat your cardiac disease. The purpose of the research is to compare two devices used for treating the part of your wrist where the artery will be used to insert the tube (called a catheter) all the way up your arm and into the chest to reach the blood vessels of the heart. Both devices are approved by the Food and Drug Administration (FDA) for this use and have already been used by your doctor on patients undergoing transradial procedures. It is believed that the use of both devices in combination compared to the hemostasis band (TR band) alone will shorten the time that it takes to 'seal' the artery, resulting in a shorter period of time that you would need to wear the hemostasis band. We expect to enroll 150 patients from our hospital for this study.

WHAT IS THE STUDY ABOUT AND WHY ARE WE DOING IT?

This is a very important study designed to resolve a key question that one device (StatSeal) used to prevent bleeding from the site of access in the blood vessel of your wrist, might be better than another device used for the same purpose (TR Band).

WHAT IS THE PURPOSE OF THIS STUDY?

You are being asked to consent to participate in a research study because your doctor has determined that you need a cardiac catheterization procedure to treat your cardiac disease. The purpose of the research is to compare two devices used for treating the part of your wrist where the artery will be accessed. Both devices are approved by the FDA for this use and have already been used by your doctor on patients undergoing transradial procedures. It is believed that the use of both devices in combination compared to the hemostasis band (TR band) alone will shorten the time that it takes to 'seal' the artery, resulting in a shorter period of time that you would need to wear the hemostasis band.

The first device used is a hemostasis band (TR band), a compression device designed to assist in ensuring that bleeding does not occur from the radial artery after this artery has been used to insert the catheter for the catheterization procedure.

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This device is routinely used to control bleeding from radial artery at the wrist in our hospital. . The band assists in maintaining openness of the radial artery at the time of the hemostasis in order to prevent future radial artery blockage. It is typically applied immediately post procedure and is left on the patient for 1-2 hours after catheterization is performed. Following this time, air is removed every 15 minutes to see if hemostasis has occurred. If bleeding occurs, then one to two mL (milliliters) of air will be placed back into the band for another 15 minutes.

The second device that will be used is called “StatSeal Advanced”, a small, dime sized disc made of a chemical compound (Potassium Ferrate) that is known to speed up the clotting of the blood it comes in contact with. This disc is placed on your wrist at the site of the needle puncture and covered with a clear, sterile bandage. Then, a standard hemostasis band (TR band) is placed over it and inflated by the study doctor. Once the hemostasis band is removed, the disc & bandage will stay in place on the puncture site for 24 hours. You will remove the bandage the next day, leaving some remaining parts of the disc in place, kind of like a ‘scab’ from a cut. It will eventually wash off when washing or showering.

TR Band device (First device)

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StatSeal device to control bleeding (Second device)

Both of these devices are used as part of standard of care at the LBVA.

HOW LONG WILL I BE IN THE STUDY?
Your participation will last for approximately 24 hours after the procedure.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?
The main procedures in the study involve cardiac catheterization which is a standard of care procedure used to diagnose and treat cardiovascular conditions. After this procedure, a device called a hemostasis band is used to achieve initial healing of the puncture site and control any bleeding after the catheters are removed.

The device that you will receive will be determined once your catheterization procedure is completed. You will be randomly assigned to one of the two methods. However, you will know which group you are assigned to as the StatSeal Advanced disc, if you are assigned to that group, is visible under the hemostasis band. If your procedure cannot be completed using the artery in your wrist, you will not continue in the study and will not be assigned to one of these conditions. Your study doctor will advise you on the best course of treatment for you.

You will have a test called a Plethysmography – Oximetry or Pulse-Ox study at several time points. This test uses a pulse oximeter machine to assess the flow of blood through your arteries at the fingertip, and also uses a special device to measure the oxygen in your blood. The test will be performed once before the catheters are inserted in to your artery, and then again several times after the procedure once the hemostasis system is placed on your wrist, and one final time just before discharge home, or 24 hours later if you remain in the hospital. Both of these tests involves placing a

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small device on your thumb or index finger so it monitors blood flow in to your hand below the catheter insertion site. The pulse-ox tests will not cause any pain.

You will be involved in the study for no more than 24 hours if you are an inpatient. If you are an outpatient, the final test required under the study will be performed just before you are discharged home following your procedure. You will not need to return to the hospital for any other tests related to the study.

The procedures performed are part of standard of care. Both devices that will be used are approved by the FDA, and have both already been used by your doctor on patients undergoing transradial procedures. For purposes of this study, all procedures are performed for purposes of research

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
By participating in the research, you may experience some of the following risks and discomforts: The specific risks of a radial procedure are detailed in the consent you signed for the procedure itself. There are no additional risks related to the use of either study device. Regardless of the group you are assigned to, there is a very low risk of the radial artery being damaged or becoming blocked after the procedure. The study will measure these variables.

The currently FDA approved and marketed hemostasis band (TR band) that will be used has been associated with complications such as, but not limited to (the following listed in order from most likely to occur to least likely to occur):

- skin irritation
- general wrist discomfort
- hematoma - localized swelling filled with blood
- pseudoaneurysm – localized swelling filled with blood formed outside the arterial wall. If this occurs, it is seen at the site of entry into the artery (the radial artery) at the wrist. The symptoms of this are usually, swelling, pressure and pain at the site of the wrist.
- radial artery occlusion—blockage or closing of the radial artery. If this occurs, the symptoms might be tingling or numbness of certain

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fingers, paleness of the hand in comparison to normal, and some weakness of strength in one or two fingers, for example in the act of gripping something. On examination, the doctor might find a weaker than normal pulse at the wrist.

- failure to achieve hemostasis – inability to stop bleeding

Some known risks of the study device (StatSeal Advanced Disk) are:

- thrombosis – blood clotting
- bleeding

Every effort will be made to reduce risks in this study. There may be risks involved which are currently unforeseeable.

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You may or may not benefit by participating in the research. However, by participating in this study, your recovery time may be shorter. Additionally, your participation will help doctors in determining if the use of the StatSeal Advanced disc leads to shortened time to hemostasis, and a shorter stay in the hospital, which may then benefit other patients at the study centers and elsewhere.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO JOIN THIS STUDY?

There are alternatives to participating in the research. If you choose not to participate, you will receive LBVA standard of care, involving the TR band or the SSA device in conjunction with the TR band. The TR Band alone is more commonly used at the LBVA.

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WILL I RECEIVE COMPENSATION FOR PARTICIPATING?

You will not receive any payment for participating in the study.

WHAT ARE THE COST TO ME IF I TAKE PART IN THIS STUDY?

You will not be required to pay for research-related treatment you receive as a subject in a VA research program.

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Transradial cardiac catheterization procedures, including recovery, and the equipment, tests, and devices used are currently FDA approved and are covered by the LBVA.

Some Veterans are required to pay co-payments for medical care and services provided by VA. These co-payment requirements will continue to apply to medical care and services provided by VA that are not part of this study.

ARE BIOSPECIMENS USED AND WHO COULD PROFIT FROM THE STUDY RESULTS? HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

No biospecimens will be collected from you or used as part of this study.

Your medical records may be examined by the Department of Health and Human Services (DHHS), the VA, other international governmental regulatory agencies (including the Office of Research Oversight and the Government Accountability Office) and the Institutional Review Board (IRB) for verification of study related data. Southern California Institute for Research and Education (SCIRE) might require personal information for subject payment and/or non-VA billing. A note will be placed in your medical records indicating your participation in this research study.

The results of this study may be published in the medical literature or presented at scientific medical or educational meetings, but your name or identity will not be revealed, and your records will remain confidential unless disclosure of your identity is required by law. Because of the need to release information to the parties listed above, absolute confidentiality cannot be guaranteed.

Once you sign this informed consent, the study investigator and/or study staff will place a copy of this informed consent in your VA patient medical record.

Because this study involves articles regulated by the FDA (Food and Drug Administration), the FDA may choose to inspect research identifying you as a subject of this investigation.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

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All new findings that develop during the research which may reasonably influence your desire to continue participation in this study will be provided to you as such information becomes available. If your participation is cancelled the reasons will be explained to you.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?

In the event you are injured as a result of your participation in this research study, you should return to the Long Beach VA Medical Center immediately for evaluation. The VA will provide emergency care and appropriate medical treatment to you at no cost and in accordance with federal law and Department of Veterans Affairs policy. The Medical Center Director will provide reasonable reimbursement for emergency treatment in a non-VA facility. Compensation is not routinely available if injury should occur. You do not give up your option for legal recourse by signing this informed consent.

WHO IS SPONSORING THIS STUDY?

This study is not being sponsored by a non-VA agency, company or entity.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the Institutional Review Board (IRB). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the [list your site contact information here] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

In case there are medical problems, you are injured by the research, or you have questions or complaints about this research, you can call Dr. Arnold Seto at 562-826-8000 ext. 5486 during the day or after hours at 562-826-8000 and have the operator page the PI, Dr. Arnold Seto. If you have questions regarding your rights as a research subject or any questions, complaints, or security concerns about this study that are not answered by the investigator (including the verification of the validity of a study and authorized contacts) you may contact the Associate Chief of Staff for Research and Development for the VA Long Beach Healthcare System at (562) 826-5801.

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Voluntary Participation Statement

I have read or have had read to me all of the above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I understand what the study is about and how it is being done. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me.
I understand my rights as a research subject and I voluntarily consent to participate in this study. **I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of VA or other benefits to which I am entitled. I understand that I may withdraw my consent at any time and discontinue participation without penalty or loss of VA or other benefits to which I am entitled.** I will receive a signed copy of this consent form along with a copy of the Bill of Rights for Human Subjects in Medical Research. By signing this form, I willingly agree to participate in the research it describes.

_____	_____	_____
Subject's Signature	**Name (print)**	**Date**
_____	_____	_____
Signature of Person Conducting the Consent Discussion	**Name (print)**	**Date**

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