Official Title: Use of Dermabond in Mitigation of Spinal Cord Stimulation Trial Lead Migration
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Atrium Health
Wake Forest Baptist

Department of Anesthesiology-Section on Pain Medicine

USE OF DERMABOND IN MITIGATION OF SPINAL CORD STIMULATION TRIAL LEAD MIGRATION

Informed Consent Form to Participate in Research
Lyle Hamsher, MD: Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to determine if the use of Dermabond to secure the trial leads at the insertion site during the spinal cord stimulator trial lead procedure will lead to less lead migration (movement) at the end of the trial period (typically 5-8 days) than just securing the trial lead with a suture by itself. Both methods of securing trial leads are currently done at our facility depending on the surgical provider placing them. This study will tell us if there is any difference trial lead movement based on how it was secured.

You are invited to be in this study because you are undergoing a spinal cord stimulator trial lead placement (in anticipation of your potentially receiving a permanent spinal cord stimulator implant). This procedure is a required diagnostic implantation in order to show if the spinal cord stimulator would be effective in treating your chronic pain. During the trial the distal end of the leads are within the thoracic and lumbar epidural space, and the proximal end of the leads are externalized and can be prone to migration. The leads are typically secure in place with tape alone or tape and suture and/or dermabond. Your participation in this research will involve being randomized like the flip of a coin to having one of your trial leads secured with only a suture while the second lead is secured with Dermabond and a suture. The randomization will tell us which lead to include Dermabond on. You will be evaluated by x-ray as is standard of care between 5-8 days after your procedure where your surgical provider can see if there was any movement of the lead from their initial placement until that time. Your total participation in this study will last until your follow-up appointment with your provider approximately a week after your procedure.

You are going to be having these spinal cord stimulator trial leads placed and they will be secured in one of these 2 methods by your medical provider. Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include to not have your trial leads secured in a randomized manner and just let your surgical provider secure them in the way that they prefer.

You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator at [redacted] (research nurse).

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to participate in a research study. During the trial the distal end of the leads are within the thoracic and lumbar epidural space, and the proximal end of the leads are externalized and can be prone to migration. The leads are typically secured in place with tape alone or tape and suture and/or dermabond. The purpose of this research is to determine if the use of Dermabond to secure the trial leads at the insertion site during the spinal cord stimulator trial leads procedure will lead to less lead migration (or movement) at the end of the trial period (typically 5-8 days) than just securing the trial lead with a suture by itself. With each lead secured differently we will then be able to compare the amount of each trial lead moved, if any when evaluated at your follow up clinic visit. Both methods of securing trial leads are currently done at our facility depending on the provider placing them. This study will tell us if there is any difference trial lead movement based on how it was secured.

WHY IS THIS STUDY BEING DONE?

You are invited to be in this study because you are undergoing a spinal cord stimulator trial lead placement (in anticipation of your potentially receiving a permanent spinal cord stimulator implant). As discussed with you by your surgical provider, 2 leads are placed in your spinal space and are identified as left or right. Depending on the surgical provider, both suture alone as well as Dermabond + suture are used, based on their individual preference. As part of your qualification to receive this implant you are required to have a trial lead placement done to determine its effectiveness in treating your pain. Your participation in this research will involve being randomized like the flip of a coin to having one of your trial leads secured with only a suture while the second lead is secured with Dermabond and a suture. The randomization will tell us which lead to include Dermabond on. You will be evaluated by x-ray as is standard of

care between 5-8 days after your procedure where your surgical provider can see if there was any movement of the lead from their initial placement until that time. Your total participation in this study will last until your follow-up appointment with your provider approximately a week after your procedure. A short questionnaire will be administered at the follow-up appointment.

How Many People Will Take Part in the Study?

Fifty-six people at Atrium Health Wake Forest Baptist will take part in this study.

What Is Involved in the Study?

You will arrive at the pain medicine clinic for your scheduled procedure of placement of spinal cord stimulator trial leads. As explained prior to this procedure being scheduled by your surgical provider, you will have 2 stimulator trial leads placed in your epidural space. They are identified as left and right leads during the course of your procedure. This is to determine if you receive pain relief and would benefit from a permanent spinal cord stimulator in the future. As part of this trial lead placement, the 2 leads are secured on your back to prevent movement (or migration) of these leads during the time period being evaluated. To assist in preventing these trial leads from moving where your surgical provider has placed them, they are secured after placement with a suture alone or a combination of suture + Dermabond. For this study we are seeing which method of securing these leads is most effective. For this study, we would like to randomize you (like the flip of a coin) for one of the leads to be secured with just a suture while the second lead is secured with both a suture + Dermabond.

You will undergo your scheduled procedure as discussed with your surgical provider. At the end of the procedure one of the trial leads will be secured in place with only a suture while the other lead is secured in place with a suture + Dermabond. The trial leads are attached to the stimulator and you will be discharged home. You will return to the clinic to see your surgical provider within 5-8 days as you normally would to have x-rays and to determine how effective this treatment was in treating your pain. The x-rays will show if during the time period of you doing your normal activities at home the spinal cord stimulator trial leads moved out of position or not, as well as which method was most effective, if any, at securing these leads.

How Long Will I Be in the Study?

You will be in the study for 5-8 days, depending on when your follow-up appointment is with your medical provider. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first.

What Are the Risks of the Study?

This study is comparing two approved methods for treating your condition. You will be randomly assigned to one of the two groups. It is possible that one treatment group may have a

better response than the other. Therefore there is a risk that you may be assigned to a group that does not perform as well as its comparison. An allergy to Dermabond may be experienced, which would include such reactions as redness, itching, or hives at the application site.

Are There Benefits to Taking Part in the Study?

You are not expected to receive benefit from participating in this study. It is anticipated that we can discover information from your participation that will assist medical providers in knowing which is the best way to secure spinal cord stimulator trial leads to avoid migration.

What Other Choices Are There?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Alternatives include having your trial leads secured in the way that your current medical provider desires, whether it be with suture or with a combination of Dermabond and suture.

What Are the Costs?

All costs related to your spinal cord stimulator trial lead procedure are your responsibility. This study is only evaluating the best way to secure these trial leads after placement.

Will Your Research Records be Confidential?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

Will You Be Paid for Participating?

You will receive no payment or other compensation for taking part in this study.

Who is Sponsoring this Study?

This study is an investigator initiated clinical trial and has no outside sponsor funding the principal investigator for the conduct of this study.

What Happens if You Experience an Injury or Illness as a Result of Participating in this Study?

Atrium Health Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent

research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Lyle Hamsher at [redacted] or after hours at [redacted].

What About My Health Information?

In this research study, any information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. Some of the information we will collect for this research study includes**:** age, race, ethnicity, surgical procedure, medications received, and pain scores.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer with two factor authentication required for access.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons including carrying out the study, determining the results of the study, making sure the study is being done correctly, providing required reports, and getting approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers, or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health

Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless you have provided your written authorization.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least 6 years after the study is finished. At that point, any research information not already in your medical record will destroyed. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center.

You can tell Dr. Hamsher that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Lyle Hamsher, MD
[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

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 web site at any time.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because you no longer meet inclusion criteria to participate in the study or your condition has worsened. Information that identifies you may be removed from the data that are collected as part of this study and could be used for future research or shared with others without additional consent. Clinically relevant research results will be not be directly disclosed to you but will be published in lieu of individual contact.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

Whom Do I Call if I Have Questions or Problems?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Lyle Hamsher, at [redacted] during regular business hours or after hours at [redacted] after regular business hours.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like

to discuss problems or concerns, have questions, or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form to keep for your records.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm