High frequency sacral root stimulation to improve bladder and bowel emptying following SCI

NCT05214378

June 15, 2022

Participant Name: _____ Date: _____

Title of Study: High frequency sacral root stimulation to improve bladder and bowel emptying following SCI

Principal Investigator: Dennis Bourbeau, PhD VA Facility: Louis Stokes Cleveland VAMC

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the Department of Veterans Affairs. Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

You do not have to participate in this study. You may stop your participation in this study at any time without changing your current or future relations with Louis Stokes Cleveland VAMC or its doctors.

If you decide to participate in this study, you will be told about any new information learned during the course of the study that might cause you to change your mind about staying in the study. If you withdraw, we will still provide you with information regarding possible impacts to your health status or future health care decisions.

Neurogenic bladder dysfunction occurs after spinal cord injury (SCI). It is a problem that often includes detrusor-sphincter-dyssynergia (DSD), which results in difficulty emptying the bladder due to reflex urethral sphincter contractions during bladder emptying. Individuals with DSD typically require a catheter to empty their bladder. Some people have received an implanted device that stimulates the spinal nerves that connect to the bladder to empty the bladder without a catheter. However, this procedure usually also includes cutting nerves to stop unwanted reflexes. For this study, we are testing a new electrical stimulation pattern to determine if it can help achieve bladder emptying without having to cut nerves. Individuals with SCI who have received an implanted sacral root electrical stimulation device are being asked to participate in this research to test the effectiveness of electrical stimulation to relax the urethral sphincter and promote bladder emptying.

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WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this 2-year study is to determine if bladder emptying can be achieved using electrical stimulation of the sacral roots at certain frequencies. Approximately 8 people will be asked to participate in this study. If you are a Veteran and are usually seen at Louis Stokes Cleveland VAMC, then you will participate in this study at the Louis Stokes Cleveland VAMC. This study will require two visits over a span of one month.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

We hope the information learned from this study will benefit other patients with neurogenic bladder dysfunction in the future. Bladder dysfunction is recognized as a significant problem in individuals with neurologic disorders or injury such as spinal cord injury. We are developing different approaches that have the potential to improve or restore bladder control for individuals with bladder dysfunction.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of the study is Dennis Bourbeau, PhD at the Louis Stokes Cleveland VAMC. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: [redacted].

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

<u>Visit 1</u>

The duration of this visit is expected to take about one hour. During this visit, we will review what will happen, including reviewing this consent form. If you consent to participate in this study, then a sample of your urine will be collected and tested to determine if you have a urinary tract infection. In the days following this initial visit, you will be prescribed an antibiotic, which you will pick up from Pharmacy, to take in the

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days before and after participation in this study to prevent a urinary tract infection. We will contact you in the days leading up to the second visit to remind you about the antibiotic.

Visit 2

This second visit will occur within 2 – 30 days after Visit 1. This visit will last about 4 hours. During this visit, we will test electrical stimulation while measuring your bladder activity using a standard urodynamics test.

Standard Urodynamics Test: In a clinical setting, a nurse or doctor will put a blood pressure cuff on your arm to monitor your blood pressure. A nurse or doctor will put a catheter of about 4 millimeters diameter into your bladder through your urethra. The urethra is the tube from your bladder to the outside of your body. The catheter will allow urine to be taken out and sterile saline (saltwater) to be put in and will also make it possible to record the pressure in your bladder and in your urethra. The catheter is shaped like a tube. Sticker electrodes will be placed on the skin around your anus to measure muscle contractions of your anus and pelvis. A small tube will also be placed into the anus to record the pressure in the lower bowel. Sterile saline will be put into the bladder through the tube in the urethra while recording the pressure in the bladder and urethra and watching for electrical activity of the muscles around the anus.

Electrical Stimulation

You already use an implanted device to stimulate your spinal roots for bladder emptying. We will use an external (not implanted) stimulation controller that is compatible with your system to test different stimulation patterns. Your bladder will be filled and emptied up to six times. While the bladder is full, stimulation will be applied, and we will measure your bladder responses to that stimulation. At the end of the study, you will resume using your device as normal.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.
- Tell the investigator or research staff if you believe you might be pregnant
- Ask questions as you think of them.

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WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?

Tissue Damage – rare. There is a small risk that the neural tissue may be damaged by the application of electrical stimulation. This risk will be minimized by applying stimulation within amplitude and duration parameters that were safe and effective in chronic preclinical experiments.

Urinary tract infection: This risk is uncommon. There is a risk of less than 10% that you will develop a urinary tract infection (UTI) following urodynamics in this study. This risk will be minimized by performing catheterization with sterile technique and by taking antibiotics before and after the experiment as prescribed. If you experience signs or symptoms of a UTI (such as blood in the urine, frequency, urgency, increased spasms, fever, chills, and/or pain in the lower back) after the study, please contact a member of the study team. You will be advised on how to proceed for medical treatment.

Urethral trauma: This risk is uncommon. There is a small risk, which we estimate at approximately 2%, that you will experience mild trauma to the urethra (the tube that runs from your bladder to outside your body) as a result of catheterization for this study. Such trauma might result in a small amount of bleeding from the surface of the urethra, similar to that seen from the gums on vigorous tooth-brushing. This risk will be minimized by lubricating the catheter with sterile water-soluble gel and by careful catheterization technique.

Discomfort during urodynamic testing: You may experience some discomfort from lying down for up to four hours at a time during these procedures. If so, the investigators will assist you in changing position to become more comfortable. The investigators will assist you in changing position at least every 2 hours, if the procedures last that long, to reduce the risk of pressure sores.

Reproductive Health/Sexual Activity: The effects on the developing child of using electrical stimulation during pregnancy and the risk of birth defects are unknown. Therefore, women who are pregnant or breastfeeding may not participate in this study.

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WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

There is no benefit to you from participation in this research. We hope the information learned from this study will benefit other patients with neurogenic bladder dysfunction in the future. Bladder dysfunction is recognized as a significant problem in individuals with neurologic disorders or injury such as spinal cord injury. We are developing different approaches that have the potential to improve or restore bladder control for individuals with bladder dysfunction.

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

There is no other option except to not participate in this trial.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

We will make every effort to keep your research records private, but confidentiality cannot be assured. The Cleveland VA Medical Center has no control over the use of this information once it is released. The information about you that is collected in this study may be combined with information gathered from public sources or other research studies. This information may be used for purposes unrelated to this research and could potentially be used to identify you.

Health Information Portability and Accountability Act (HIPAA)

There are rules to protect your private information. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form, you provide your permission called your 'authorization,' for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. The study team may also collect other information including your name, address, phone number, and date of birth.

The research team may also need to disclose the information to others as part of the study progress. These others may include the following:

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- VA Institutional Review Board
- The local VA medical facility Human Research Protections Program
- The Food and Drug Administration (FDA)
- Department of Health and Human Services agencies
- MetroHealth Institutional Review Board
- National Committee for Quality Assurance
- Greenphire
- Cleveland VA Medical Research and Education Foundation (CVAMREF)

Your health information disclosed pursuant to this authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient.

While this study is being conducted you will have access to your research related health records.

This will not affect your VA healthcare, including your doctor's ability to see your records as part of your normal care and will not affect your right to have access to the research records after the study is completed.

You can revoke this authorization, in writing, at any time. To revoke your authorization, you must write to the Release of Information Office at this facility o you can ask a member of the research team to give you a form to revoke the authorization. Your request will be valid when the Release of Information Office receives it. If you revoke this authorization, you will not be able to continue to participate in the study. This will not affect your rights as a VHA patient to treatment or benefit outside of the study.

If you revoke this authorization, Dennis Bourbeau, PhD and his research team can continue to use information about you that was collected before receipt of the revocation. The research team will not collect information about you after you revoke the authorization.

Treatment, payment or enrollment/eligibility for benefits cannot be conditioned on you signing this authorization. This authorization will expire at the end of the research study unless revoked prior to that time.

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Greenphire ClinCard Reimbursement Program: Greenphire is a company working together with Cleveland VA Medical Research and Education Foundation (CVAMREF)to manage your compensation. You will be issued a Greenphire ClinCard, which works like a debit card. When a follow-up visit is completed, funds will be approved and loaded onto your card. The funds will be available within one business day and can be used at your discretion. For Greenphire to be able to reimburse you via the ClinCard, Greenphire needs to collect certain information about you from your study doctor, including your name, address, and date of birth.

All information about you is stored securely and is deleted from Greenphire's system once the study has been completed. Your information will not be shared with any third parties (including the sponsor) and will be kept completely confidential.

By signing this consent form, you consent to provide the before-mentioned personal information that is needed to set up payments. You agree that the information you provide is used by Greenphire to perform reimbursement payments to you.

By registering with the ClinCard system and using the ClinCard, you consent to participate in the ClinCard program. You may be required to provide your taxpayer ID (Social Security #) if thresholds for IRS (Internal Revenue Service) reporting are met. This will only happen if you receive a total of $600 in a year while participating in any research study at Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC)

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

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

WILL I BE PAID FOR PARTICIPATION IN THIS STUDY?

If you do not have a private vehicle, transportation will be provided to you. You will receive $25 at the end of Visit 1 and $50 at the end of Visit 2. It will be paid using a ClinCard, which is a re-loadable debit card, paid at each visit. The total compensation that you may receive is $75.

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If you do not complete the study, for any reason, you will only be paid for each study visit you do complete. If you have any questions regarding your compensation for participation, please contact the study staff.

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

Any procedure has possible risks and discomfort. The procedures in this study may cause all, some, or none of the risks or side effects listed. If such problems occur during the course of the study, contact the study's Principal Investigator, Dr. Dennis Bourbeau at [redacted].

If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

DO I HAVE TO TAKE PART IN THE STUDY?

Taking part in this study is voluntary. By signing this consent form, you are not waiving any of your legal rights. You have the right to choose not to take part in this study. If you do not take part in the study, your doctor will still take care of you. You will not lose any benefits or medical care to which you are entitled. If you withdraw from the study, with your written permission, clinical data will continue to be collected from your medical records.

If you chose to take part, you have the right to stop at any time. You will be told of any new findings from this or other studies that may affect your health, welfare, or willingness to stay in this study.

RIGHT OF INVESTIGATOR TO TERMINATE MY

There may be instances that would require investigators to terminate your participation in this study. Investigators will stop the experiment if you demonstrate any unresolved physical or psychological discomfort or if stimulation does not have a significant effect on your bladder.

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

If you have questions about any part of the study now or in the future, or if you wish to communicate concerns or a complaint you should contact Dennis Bourbeau, PhD, who may be reached at [redacted].

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 VA Institution Review Board. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the [redacted] if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

WILL I BE TOLD NEW INFORMATION ABOUT THIS STUDY?

Sometimes during the course of a research study, new information becomes available that is being studied that might change a person's decision to stay in the study. If this happens, your research doctor will tell you about it and discuss with you whether you

want to continue in the study. If you decide to withdraw from the study, your research doctor will arrange for your medical care to continue. If you decide to continue in the study, you might be asked to sign an updated informed consent form. Your research doctor could also decide it to be in your best interests to withdraw you from the study. If so, he or she will explain the reasons and arrange for your usual medical care to continue.

WHO COULD PROFIT FROM THE STUDY RESULTS?

This study is being funded by the Department of Veterans Affairs. Portions of Dr. Dennis Bourbeau and his research team's salaries are being paid by this grant.

The principal investigator and/or other members of the research team have no significant financial interest in the product being investigated in this study.

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Principal Investigator: Dennis Bourbeau, PhD VA Facility: Louis Stokes Cleveland VAMC

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

Dr./Mr./Ms (study staff) _____ has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been told of other choices of treatment available to you. You have been given the chance to ask questions and obtain answers.

By signing this document below, you voluntarily consent to participate in this. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this form.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

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