Reducing anticholinergic bladder medication use in spinal cord injury with home neuromodulation

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CONSENT TO TAKE PART IN RESEARCH

Simple Study Title: Home TTNS RCT HSC-MS-19-0518
Full Study Title: Reducing anticholinergic bladder medication use in spinal cord injury with home neuromodulation
Study Sponsor: UTHealth KL2 Award
Principal Investigator: Argyrios Stampas, MD. Dept of PM&R, UTHealth
Study Contact: Vanessa Bernal, RA, Research Assistant [redacted]

You are invited to take part in this research study because you have spinal cord injury (SCI) and perform intermittent catheterization (IC) to empty your bladder. This consent form has important information about this study to help to decide whether or not to take part in this study. Your decision to take part is voluntary. You may refuse to take part or choose to stop taking part, at any time. A decision not to take part or to stop being a part of the research project will not change the services available to you from Dr. Argyrios Stampas or the research staff at the University of Texas Health Science Center at Houston (UTHealth) and Memorial Hermann Healthcare System.

The purpose of this study is to determine if electric stimulation to the leg, called transcutaneous tibial nerve stimulation (TTNS), can improve bladder outcomes. If you choose to participate in this study, you will be asked to use TTNS at home at specific settings, maintain a diary of your bladder program, TTNS use, and settings, and try to reduce your oral bladder medications. The total amount of time you will be in this study is 3 months.

There are potential risks involved with this study that are described in this document. Some known risks include increased incontinence from reducing bladder medications and skin irritation from surface electrodes.

There may be potential benefits to you such as reducing bladder medications without increasing bladder accidents (incontinence). You may not benefit directly from your participation in this study; however, the information gained from your participation may benefit others in the future.

There are alternatives to participating in this research study, such as continuing with medications OR BOTOX® injections that may be provided by urology with insurance approval.

If you are interested in participating, please continue to read below.

What is the purpose of this research study?
The purpose of this study is to see how well TTNS works at treating people with paraplegia from SCI that perform intermittent catheterization to empty their bladder. This study will test the safety of the TTNS. TTNS has not been approved by the Food and Drug Administration (FDA); therefore it is called an investigational device.

UTHealth KL2 Award is paying UTHealth for their work on this study.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This will not include information that can identify you. After the study has ended, website will include a summary of the results. You can search this website at any time.

Who is being asked to take part in this study?

You are being asked to take part in this research study because you have paraplegia from SCI and perform intermittent catheterization to empty your bladder. This study is being conducted at TIRR Memorial Hermann. About 60 people will take part in the study in this country, all from TIRR Memorial Hermann.

What will happen if I take part in this study?

If you agree and are able to take part in this study, you will undergo the following procedures:

- You will come into the clinic to see if you qualify for the study. We will use the TTNS device to see if we are able to stimulate the correct nerve using the device. If so, you will be shown how to place the electrodes and how to use the device. This may be recorded on your cell phone or other device so you can refer to the video later if you have questions. You will also be provided written instructions for how to use the TTNS device at home.
- You will be randomly assigned (similar to flipping a coin) to two different settings of TTNS to help determine which setting is better. This type of study is called a randomized control trial.
- In clinic, you will be asked questions regarding side effects of bladder medications and incontinence and the impact on quality of life. At the end of 3 months of use, we will call you to ask you the same questions to see if there is a difference.
- You will take the device home and use it to provide stimulation to your leg for 30 minutes, 5 days weekly, for 3 months. You will be called weekly to remind you to complete the TTNS and medication log and make sure you are not having any problems with the device.
- After 2 weeks of using the device, you will be directed to reduce the use of your bladder medications. If you have worsening bladder problems (for example incontinence, bladder spasms), call the study team [redacted] and they may recommend restarting those medications.
- You will be provided with a diary to fill out the following daily:
    - TTNS use and settings
    - Bladder medication use
- You will also be asked to fill a bladder diary for 2 days when you begin the trial, and then every 4 weeks. This is used to record the frequency and amount of catheterizations performed, and episodes of leaking and incontinence.
- The research assistant will contact you weekly for the TTNS and medication log. The research assistant will also contact you to remind you to collect the bladder diary information as well as a monthly bladder survey.
- At the end of the trial, you can keep the device for continued use.

If you agree to take part in this study you will be randomized (similar to flipping a coin) to receive one of 2 doses of TTNS, high stimulation (submotor) or low stimulation (1 mA). It is not known whether TTNS will be of benefit. For this reason, we are using different doses. This will allow a careful comparison to study the benefits and side effects of TTNS. There is a 50% chance you will receive TTNS high stimulation (submotor) and a 50% chance that you will receive TTNS at low stimulation (1 mA). Your doctor will not know which dose of TTNS you are receiving.

Listed below are exams, tests, and procedures that need to be done as part of this study to monitor your safety and health, but may not be included in the usual care. We will use them to carefully follow the effects of the study treatment, including preventing and managing side effects.

- Clinical demographics, medical problems, and Neurologic Exam findings from interview with subjects, exam, and medical record review.
- Bladder diary will include:
    - use of TTNS with amperage and presence of toe flexion, and pain score 0-10
    - log of bladder medication use
    - log of catheterization, volumes
    - log of incontinence episodes

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  - Description of other observed changes, including but not limited to: fatigue, vision changes, mental status, bowel program changes, and sexual function changes.
- Surveys:
  - I-QOL at baseline initial visit and then at 3-month follow-up. Can be conducted over phone.
  - NBSS at baseline and then every 4 weeks. Can be conducted over phone.
  - Anticholinergic survey at baseline and then at 3-month follow-up. Can be conducted over phone.
  - TTNS Satisfaction survey at the end of the trial

How long will you be in the study?
If you agree to take part, your participation will last for 3 months and will involve only the initial clinic visit, plus weekly phone calls from the research assistant.

What choices do you have other than this study?
You may select other options than being in this research study. Usual approach is to increase medications if incontinence increases, and/or consult with urology for other treatment options.

What are the risks of taking part in this study?
There are both risks and benefits to taking part in this study. It is important for you to think carefully about these as you make your decision. There is also a possible risk of breach of confidentiality.

If you choose to take part in this study, there is a risk that the TTNS may not be as good as the bladder medications in treating your condition.

There is also a risk that you could have side effects from the TTNS. These side effects may be worse and may be different than you would get with the usual treatment.

Some of the most common side effects that the study doctors know about are:

Transcutaneous electric stimulation of the leg is well-tolerated in acute rehabilitation and commonly used. The most common side effect from electric stimulation with surface electrodes includes:

- pain which may or may not cause autonomic dysreflexia
- skin irritation

The electric stimulation parameters can be adjusted to eliminate pain. If skin irritation occurs, it usually resolves spontaneously. Some people may have sensitivity to the electrode adhesive, making the irritation worse. Hypo-allergenic electrodes will be used in these cases.

In cases where the electric stimulation causes discomfort, you may experience autonomic dysreflexia (AD). Autonomic dysreflexia is a response of elevated blood pressure due to a painful stimulus in spinal cord injury. This does not occur in all people with SCI. In those at risk or with a known history of AD, they will be reminded about the signs and symptoms of AD, and the treatment they should have available to them at their residence. A prescription for medication for AD will be provided for those without medication at home. We will try TTNS in clinic and record your blood pressure to see if it does cause AD. You cannot participate in this study if AD occurs in the clinic trial.

Should AD occur at home, notify the research team and stop using the electric stimulation until it is discussed with the research team.

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Additionally, some of the less common side effects that the study doctors know about are:

- There may be an increased risk of bladder infection
- Incontinence (bladder leaking) due to stopping your bladder medication.

There may be some risks that the study doctors do not yet know about.

Female:
Being part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a women able to become pregnant and sexually active with a male partner, you may not participate as the risks to the fetus are unknown. If you become sexually active while in the 4-week study, you must agree to use appropriate contraceptive measures while taking part in this study and for 1 month afterward. Medically acceptable contraceptives include: (1) surgical sterilization (such as tubal ligation or hysterectomy), 2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with a spermicide, or (4) intrauterine device (IUD). If you become pregnant while taking part in this study or if you have unprotected sex, you must inform the study doctor immediately.

The research may hurt an embryo or fetus in ways we do not currently know.

Male:
If you are a man, taking part in this research study may damage your sperm, which could cause harm to a child that you may father while on this study. If you are sexually active, it is very important that you check with your study doctor about what types of birth control or pregnancy prevention to use during the study and for 1 months afterward. If your partner becomes pregnant while taking part in this study or if you have unprotected sex, you must inform the study doctor immediately.

What are the benefits to taking part in this study?
There is some evidence in people with SCI that the TTNS can be used similarly to bladder medications to maintain continence. However, we do not know if this will happen in everyone with SCI. This study may help the study doctors learn things that may help other people in the future.

Can you stop taking part in this study?
You may decide to stop taking part in the study at any time. To withdraw from the study, please contact Argyrios Stampas, MD at [redacted].

Your doctor or the sponsor can stop the study at any time. Your doctor or the sponsor may stop your participation in the study if your condition worsens, the study is stopped, the study drug is no longer available, you do not meet all the requirements of the study, or the study is not in your best interest. If your participation in the study is stopped, your doctor will discuss other options for your treatment.

If you stop participating in this study, the information already collected about you will still be used in the data analysis. However, no further information will be collected without your permission.

While taking part in this study, the study team will notify you of new information that may become available and could affect your willingness to stay in the study.

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What happens if you are injured during the study?
If you suffer an injury as a result of taking part in this research study, please understand that nothing has been arranged to provide free treatment of the injury or any other type of payment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You should report any such injury to Argyrios Stampas, MD at [redacted]. You will not give up any of your legal rights by signing this consent form.

What are the costs of taking part in this study?
The sponsor will pay for the special tests and examinations that are required by this study and not otherwise part of your standard medical care.

For completing the daily TTNS and bladder medication log, you will be provided $20 monthly for your effort. For each day of the voiding dairy collected, you will be provided $10, for a maximum of $20 monthly. If after 4 weeks you have provided complete data, you will be provided with an additional $10. Therefore, you may be compensated $170 for the 3 months of your effort in completing the diary.

You will be issued gift card that can electronically receive the funds. All information is stored in a secure fashion and will be deleted from the system once the study has been completed.

How will privacy and confidentiality be protected?
Your privacy is important and your participation in this study will be kept confidential. However, absolute confidentiality cannot be guaranteed.

If you sign this document, you give permission to UTHealth and Memorial Hermann Healthcare System to use and disclose (release) your health information. The health information that we may use or disclose for this research includes all information in a medical record, results of physical examinations, medical history, lab tests, or certain health information indicating or relating to your SCI. Please understand that health information used and disclosed may include information relating to HIV infection, drug abuse, alcohol abuse, behavioral health, and psychiatric care.

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. After we remove all identifiers, the information may be used for future research or shared with other researchers without your additional informed consent.

People who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect your health information and may share your information with others without your permission, if permitted by laws governing them. You will not be personally identified in any reports or publications that may result from this study. If all information that does or can identify you is removed from your health information, the remaining information will no longer be subject to this authorization and may be used or disclosed for other purposes.

Representatives of the organizations listed below will see your name and other personal identifiers when they review your research records and medical records for the purposes of verifying study data:

- Representatives of UTHealth and/or Memorial Hermann Health System
- Representatives from the U.S. Food and Drug Administration (FDA)
- Representatives of the sponsor of this research including contract research organizations
- Companies engaged with the UTHealth for the commercialization of the results of the research study

Please note that you do not have to sign this Authorization, but if you do not, you may not participate in this research study. UTHealth and Memorial Hermann Health System may not withhold treatment or refuse treating you if you do not sign this Authorization.

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You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, researchers may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must contact Argyrios Stampas, MD in writing at TIRR Memorial Hermann, [redacted].

This Authorization will expire 15 years after the end of the study.

Whom can you contact if you have questions about the study?
If you have questions at any time about this research study, please feel free to contact the Vanessa Bernal at [redacted], as they will be glad to answer your questions. You can contact the study team to discuss problems, report injuries, voice concerns, obtain information in addition to asking questions about the research.

The Committee for Protection of Human Subjects at the University of Texas Health Science Center has reviewed this research study. You may contact them for any questions about your rights as a research subject, and to discuss any concerns, comments, or complaints about taking part in a research study at [redacted].

SIGNATURES

Sign below only if you understand the information given to you about the research and you choose to take part in this research study. Make sure that all your questions have been answered. If you decide to take part in this research study, a copy of this signed consent form will be given to you.

Printed Name of Subject	Signature of Subject	Date	Time
Printed Name of Legally Authorized Representative	Signature of Legally Authorized Representative	Date	Time
Printed Name of Person Obtaining Informed Consent	Signature of Person Obtaining Informed Consent	Date	Time

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