Clinical Characterization of Burst Spinal Cord Stimulation for Chronic Pain Management

NCT03718325

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

1. KEY INFORMATION ABOUT THE RESEARCHERS AND THIS STUDY

Study title:

Clinical characterization of burst spinal cord stimulation for chronic pain management.

Company or agency sponsoring the study:

Michigan Institute for Clinical & Health Research Education and Mentoring Group (MICHR-EMG)

Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):

Principal Investigator: Vishwanath Sankarasubramanian, PhD, Department of Biomedical Engineering, University of Michigan

Study Coordinator: Sana Shaikh, MD, Department of Anesthesiology, University of Michigan

1.1 Key Study Information

You may be eligible to take part in a research study. This form contains information that will help you decide whether to join the study. All of the information in this form is important. Take time to carefully review this information. After you finish, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others, such as your friends, family, or other doctors about your possible participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you do, be sure you understand what the study is about.

2. PURPOSE OF THIS STUDY

2.1 Study purpose:

Doctors sometimes treat chronic pain with devices that send mild electrical currents into the spinal cord. This type of treatment is referred to as neurostimulation. A common form of neurostimulation therapy is spinal cord stimulation (SCS).

Recently, a new form of SCS therapy, called **burst spinal cord stimulation** (Burst-SCS) is available to treat chronic pain. **In this study, we want to learn more about how Burst-SCS works to reduce pain**. To find out, we will examine chronic pain patients who have been deemed candidates for Burst-SCS therapy, and who have already been selected to receive a temporary externalized trial of Burst-SCS from their own doctors as part of their standard clinical care.

3. WHO MAY PARTICIPATE IN THE STUDY

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. **Whether or not you participate in this study will have no effect on your standard clinical care for chronic pain management.**

3.1 Who CAN take part in this study?

Chronic pain patients: People who suffer from chronic pain and who are scheduled to receive a temporary externalized trial of Burst-SCS from their own doctors as part of their standard clinical care for chronic pain management.

- You are at least 18 years old
- You can speak, read, and understand English

You CANNOT take part in this study if:

- You are pregnant
- You have artificial nails, nail enhancements, or nail extensions (within the past year that cover any part of either thumbnail)
- You are unable or unwilling to undergo any of the study tests
- You have any other conditions or circumstances that the study team believes would interfere with your participation

3.2 How many people are expected to take part in this study?

We expect to enroll **20 chronic pain patients** in this study.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you meet eligibility criteria, you will be asked if you would like to enroll in the study. If you enroll, we will invite you to be part of the following study visits. **Participation involves up to five visits**. Visits 2-5 include two main session types: 1) **behavioral session** that involves assessment of your pain using several questionnaires and sensory testing procedures, and/or 2) **programming session** that involves adjusting the settings on your SCS stimulator.

Visit 1: Screening and enrollment visit

You will visit our Back and Pain Center clinic at the Burlington building in Ann Arbor. At this visit, we will find out if this study is right for you and, if so, enroll you in the study. We will ask you about your medical, social and psychiatric history and perform various clinical assessments. We will ask you to complete a set of questionnaires about your treatment history, symptoms of chronic pain, and impact of chronic pain on your daily life. We will also collect other additional information from you, such as demographics, sociodemographics, and concomitant medications. We will collect your vital signs (heart rate, blood pressure, respiration rate, and body temperature), height, and weight. We will also show you the devices to be used in this study. This will give you an opportunity to practice the tests, familiarize yourself with the study devices and ask any questions you may have about them.

If we find that you don't qualify for the study, your participation will be over. If you do qualify and you are interested in participating in the study, we will schedule your next visit(s).

Visit 2: Pre-implantation visit

Behavioral session: You will come back to our Back and Pain Center clinic at the Burlington building for a behavioral session. It is possible that this session may occur on the same day as the screening and enrollment visit. During this session, we will collect your vital signs (heart rate, blood pressure, respiration rate, and body temperature), height, and weight. We will ask you to rate your current pain on a scale. We will ask you to complete several questionnaires about your symptoms of chronic pain. We will measure your sensitivity to different stimuli, such as pressure-pain, non-painful vibration and pricking-pain. We will also do other tests (e.g. conditioned pain modulation test) to examine how your body naturally controls pain. A short summary of each of these tests is provided at the end of section 4.1.

Visit 3: First trial-phase visit

As part of your standard clinical care for chronic pain management, you will begin a "test" or "temporary externalized trial" of Burst-SCS. The purpose of this trial is to determine whether or not you are eligible to receive a permanent, implantable Burst-SCS system. At the start of the Burst-SCS trial, your doctor will implant wires (called leads) near your spinal cord. These wires will be connected to an external device that will generate mild electrical pulses that can reach your spinal cord to potentially reduce your pain.

Approximately 5-10 days after implantation of the trial lead(s) and testing of Burst-SCS, we will ask you to come back to our Back and Pain Center clinic at the Burlington building for another behavioral session and a short programming session.

Behavioral session: During this session, we will perform the same procedures as those performed in the pre-implantation visit.

Programming session: During this session, we will adjust the settings on your SCS device. When performing these adjustments, you may or may not feel the stimulation (usually as a tingling sensation). After the adjustments are complete, you will not be able to change the stimulation settings for the next 24 hours.

Visit 4: Second trial-phase visit

You will come back to our Back and Pain Center clinic at the Burlington building approximately 24 hours after visit 3 for another behavioral session and a short programming session.

Behavioral session: During this session, we will perform the same procedures as those performed in the previous visit.

Programming session: During this session, we will again adjust the settings on your SCS device. Again, when performing these adjustments, you may or may not feel the stimulation. After the adjustments are complete, you will not be able to change the stimulation settings for the next 24 hours.

Visit 5: Third trial-phase visit

Behavioral session: You will come back to our Back and Pain Center clinic at the Burlington building approximately 24 hours after visit 4 for a final behavioral session. During this session, we will perform the same procedures as those performed in the previous visits. At the end of this session, we will return your SCS device to its original settings.

The chart below outlines the five study visits.

ORDER OF STUDY VISITS	WHEN WILL IT HAPPEN?	STUDY PROCEDURES THAT WILL BE PERFORMED
Visit 1: Screening and enrollment visit	After you have been deemed a candidate for Burst-SCS therapy	-Eligibility review, informed consent -Medical history -Pain assessment (using questionnaires) -Familiarization of sensory testing procedures
Visit 2: Pre-implantation visit	Same day as the screening visit OR before the start of the SCS trial	-Pain assessment (using questionnaires) -Sensory testing
Visit 3: First trial-phase visit	Around 1 week after implantation of the leads, and during the “trial-phase” of Burst-SCS	-Pain assessment (using questionnaires) -Sensory testing -Stimulator programming
Visit 4: Second trial-phase visit	Around 1 day after visit 3	-Pain assessment (using questionnaires) -Sensory testing -Stimulator programming
Visit 5: Third trial-phase visit	Around 1 day after visit 4	-Pain assessment (using questionnaires) -Sensory testing

Sensory testing procedures

Multimodal Automated Sensory Testing (MAST): We will use MAST to assess your sensitivity to pressure-pain. We will deliver mechanical stimuli (using the MAST device) in the form of automatic ascending pressures onto your thumbnail bed.

Vibrometry: We will use vibrometry to assess your sensitivity to non-painful vibration. We will deliver vibratory, non-painful stimuli (using a handheld vibrometer) to your primary pain site and several other control sites (e.g. hand, shoulder etc).

Algometry: We will use algometry to assess your sensitivity to pressure-pain. We will deliver pressure-pain stimuli (using a handheld analog pressure algometer) to your primary pain site and several other control sites (e.g. hand, shoulder etc).

Pointed skin probe testing: We will use a handheld, pointed skin probe to deliver a fixed intensity stimulus to your primary pain site and several other control sites (e.g. hand, shoulder etc) to assess your sensitivity to pricking pain.

Conditioned Pain Modulation (CPM) testing: We will use the CPM test to examine how your body naturally controls pain. We will deliver pressure (using the algometer) to your primary pain site and control sites, before and after application of a contralateral thumbnail pressure (using MAST).

4.2 How much of my time will be needed to take part in this study?

Your total time commitment is **approximately 10 hours over the next 2-3 months**. You will participate in up to five research visits, and each visit is expected to last about 2 hours.

4.3 When will my participation in the study be over?

Your participation in the study will be over at the conclusion of **visit 5** (about 2-3 months from now).

4.4 What will happen with my information used in this study?

With appropriate permisisons, your collected information may be used for future research. The future research may be similar to this study or may be completely different.

With appropriate permissions, your collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent. We will not collect any biospecimens from you.

5. INFORMATION ABOUT STUDY RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

The known or expected risks are:

Risk related to Burst-SCS therapy:

You may be asked or you have already been asked to sign a separate consent explaining the potential risks involved with Burst-SCS therapy by your doctor as part of your standard of care.

Risk of completing surveys:

The risks associated with completing the personal symptom surveys, may cause some discomfort or personal distress.

Risks related to sensory testing:

It is possible that some of the sensory testing experiments (e.g. algometry, vibrometry, pointed skin probe testing, and CPM testing) in this study may cause some temporary physical discomfort in the body areas being tested. However, this is expected to resolve within minutes of test completion. We will halt these tests automatically if you report severe pain.

The MAST may also cause some temporary physical discomfort on the thumbnail. The MAST system includes multiple software, electrical, and mechanical safeguards to ensure that the amount of pressure applied does not exceed safe limits, including a safety release pin that you can pull to immediately release the pressure actuator from your thumb. The test is terminated at or before 10 kg/cm^2 of pressure which is a commonly-used maximum pressure level in human sensory testing and should not result in physical injury.

Risks related to electrical stimulation:

During the stimulator programming session, we will adjust the settings on your SCS device. When adjusting the settings, you may or may not feel the stimulation (usually as a tingling sensation). Once the adjustments are complete, you will not be able to change the stimulation settings for the next 24 hours. However, you may sometimes feel the tingling sensations due to positional changes (e.g. bending, lifting) and/or extreme movement. We will instruct you to avoid such movements during the 24-hour period.

Whenever using electricity to stimulate tissue, there is also the possibility of a shock hazard, including an electrical burn. However, we will only use electrical stimulators approved by the United States Food and Drug Administration for Burst-SCS. Therefore, the risk of tissue damage or electrical shock during the electrical stimulation is minimal.

Risks related to loss of confidentiality:

Additionally, there may be a risk of loss to confidentiality or privacy. The researchers involved in this study will have initial access to your name and/or other identifiable information. This is the case for any standard of care treatment.

Additional risks:

This research may extend your Burst-SCS trial by an additional 2-3 days. This additional time may increase the likelihood of some risks, such as infection or other device-related complications. However, the total duration of your trial, including both the time for your standard clinical care (~5-10 days) and research procedures (~2-3 days), will be well within the 30-day trial period that is allowed for the approved indication of Burst-SCS. Therefore, the percentage chance that you incur these additional risks is negligible.

The researchers will try to minimize these risks by:

You may refuse to answer any question on the questionnaires or surveys that may be uncomfortable. During sensory testing, we will limit the intensity of each stimulus to levels that are deemed safe and acceptable. You can also inform the study personnel to stop the sensory testing at any time that the pain or unpleasantness of the task becomes intolerable. Additionally, you can also stop the sensory testing at any time. During electrical stimulation, we will ensure that we adjust the settings of the stimulator in such a way so that you should not feel any sensations. Lastly, we will also take several measures to minimize the risk of possible loss of confidentiality. For example, we will assign you a subject number to use in place of your name for research analyses and we will electronically and physically secure your identifiable data/information. See **Section 9** of this document for more information on how the study team will protect your confidentiality and privacy.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. However, others may benefit from the knowledge gained from this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn of important new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. ALTERNATIVES TO PARTICIPATING IN THE STUDY

6.1 If I decide not to take part in this study, what other options do I have?

Your participation in this study is entirely **voluntary**. The alternative option is not to participate in the study. Your clinical care will not be affected by your decision to participate or to not participate in this study.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 “Contact Information”.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

There is no harm to you if you decide to leave the study early.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researcher's telephone number listed in Section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you are injured or in the event of a medical emergency, dial 911 or visit your nearest Emergency Room. If you believe the study has made you sick or caused you injury, contact one of the people listed in section 10 of this document (Contact Information). If taking part in the study makes you sick or causes you injury, you will have to arrange for treatment on your own, as the study will not provide medical treatment or provide any compensation to you. You or your insurance provider will be billed for all costs of treatment for sickness or injury caused by the study.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?

You will be paid **up to $380** for **participating in this study** and will be compensated as follows for each of the visits:

- $20 for completing the screening visit
- $40 for completing each behavioral session (total for up to 4 possible sessions = $160)
- $40 for questionnaires (total for up to 5 possible sessions = $200)

You may also qualify for lodging (if you live more than 1.5 hours away) or transportation as needed.

8.3 Who could profit or financially benefit from the study results?

Dr. Clauw and Dr. Harte (who are both on the study team), along with the University of Michigan, have an interest in one of the pain-testing devices (MAST device) used in this study. In the future, they might receive a part of the profits from any sales of the device.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my information?

Every effort will be made to maintain your privacy. You will be given a unique study identification number. This number will be used to record your study information. You will never be tracked through the study by name, medical record number, or other personal identifier. A log of participants' names, ID numbers, and personal information (such as home address, telephone number, and emergency contact information) will be maintained in a study file and/or on a computer in a locked area at the clinical site and/or at our research offices. Only authorized members of the research study will have permission to see these data.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your identity. All data will be retained in your study file for approximately 7 years. Then the data will be destroyed.

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.

9.2 What protected health information (PHI) about me could be seen by the researchers or by other people? Why? Who might see it?

Signing this form gives the researchers your permission to obtain, use, and share information about you for this study, and is required in order for you to take part in the study.

Medical information and billing records are protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). This type of information is called protected health information (PHI). PHI about you may be obtained from any hospital, doctor, and other health care provider involved in your care, including:

- Hospital/doctor's office records, including test results (X-rays, blood tests, urine tests, etc.)
- Mental health care records (except psychotherapy notes not kept with your medical records)
- Alcohol/substance abuse treatment records
- All records relating to your condition, the treatment you have received, and your response to the treatment
- Billing information
- Demographic information
- Personal identifiers

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials, auditors, and/or the IRB may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study

- Insurance companies or other organizations may need the information in order to pay your medical bills or other costs of your participation in the study.
- The researchers may need to use the information to create a databank of information about your condition or its treatment.
- Information about your study participation may be included in your regular University of Michigan Health System medical record.
- If you receive payment of $600 or more for taking part in research in a single year, the University of Michigan accounting department will require your name, address, social security number, payment amount, and related information. For tax reporting purposes, this information must be reported to the IRS.
- Federal or State law may require the study team to give information to government agencies. For example, to prevent harm to you or others, or for public health reasons.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

9.3 What happens to information about me after the study is over or if I cancel my permission to use my PHI?

As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:

- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission to use my PHI expire?

Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below). If you withdraw your permission, you may no longer be eligible to participate in this study.

10. CONTACT INFORMATION

10.1 Who can I contact about this study?

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished

- Express a concern about the study

Principal Investigator:	**Vishwanath Sankarasubramanian, PhD**
Mailing Address:	010-A163S NCRC, 2800 Plymouth Road Ann Arbor, MI 48109-2800
Telephone:	(734) 647-9052
Study Coordinator:	**Sana Shaikh, MD**
Mailing Address:	325 E Eisenhower Parkway, Burlington Building Ann Arbor, MI 48108
Telephone:	(734) 763-5226

You may also express a question or concern about a study by contacting the Institutional Review Board listed below:

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies, US Country Code: 001)
Fax: 734-763-1234
E-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111. *When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.*

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Print Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Consent for Participating in an Optional Sub-Study

We would like to ask your permission to retain your data and medical information for future research use. The future research may be similar to this study or may be completely different. You can take part in this study even if you decide not to let us retain your data and medical information for future research use. If you give us permission, we will use your data and medical information for future research. Even if you give us permission now to retain your data and medical information, you can change your mind later and ask us to destroy it. Keep in mind, however that once we have analyzed your data, we may not be able to take the information out for our research. We may share your data and medical information with other researchers, so that they can use it in their research. Their research may be similar to this study or may be completely different. Once we have shared your data and medical information with other researchers, we will not be able to get it back. Please respond to the following statement and CHECK either "YES" or "NO" and write your initials and today's date:

_____ Yes, I grant permission to retain my data and medical information for future use

_____ No, I do not grant permission to retain my data and medical information for future use

Contact for Future Studies

We would like to ask your permission to re-contact you about future studies on chronic pain conditions. Participation in any future studies, as with the current study, is entirely voluntary. Please respond to the following statement and CHECK either "YES" or "NO" and write your initials and todays date:

_____ Yes, I agree to be contacted for future research studies

_____ No, I do not agree to be contacted for future studies

Initials: _____

Date: _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Printed Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____