Paul Winston MD, Emily Krauss MD.

Affiliations: Island Health, UBC, University of Victoria

Patient Information and Informed Consent Form

Research Study:

STUDY: H19-03232

Measuring the efficacy of surgical and percutaneous neuroablative procedures in the management of plateaued or refractory upper-extremity spasticity patients.

Primary Investigators:

Paul Winston MD FRCPC
Medical Director of Rehabilitation and Transitions
Clinical Assistant Professor UBC and the Island Medical Program.

Emily Krauss MD MSc. FRCSC
Clinical Instructor UBC Division of Plastic Surgery

Co-Investigators:

Daniel Vincent MD FRCPC
UBC Division of Anesthesia

Address: Victoria General Hospital 1 Hospital Way V8Z6R5
Phone Number: 250-727-4221
Email: vghrehabmedicine@viha.ca

Clinic Contact: Ms. Julie Connor, Administrative Assistant.

Research Assistant: Mahdis Hashemi

SPONSOR:

Allergan, the maker of Botox, has provided an unrestricted grant to Island Health to conduct this study. No data will be shared with the Sponsor.

INTRODUCTION

You are being invited to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done, what it will involve as well as the risks and benefits so that you can make an informed decision. This process is known as informed consent. This form is part of the process of informed consent. It should give you the basic idea of the purpose and procedures of the study and what your participation will involve. This form will also explain how your medical information will be used and who may see it and outline your rights as a participant if you choose to join the study.

Please take time to read the following information carefully and if you have any questions or would like more detail about something mentioned here, or information not included here, please ask the study physician or research coordinator. Take the time to read and understand any accompanying information. You will receive a copy of this form.

BACKGROUND AND PURPOSE

You are invited to participate in a research study. Your participation must be free and voluntary. You are free to withdraw at any time. You are being asked to participate in this study because you have been diagnosed with spasticity that continues to cause you pain, discomfort, or troubles such as very poor range of motion, skin breakdown or challenges that you or your family identified.

The purpose of this study is to assess the unique treatment of spasticity that takes place in our clinic. This includes the procedures that you have been selected for including, cryoneurotomy pulsed radiofrequency, nerve surgery and muscle and tendon lengthening. All of these terms will be explained carefully to you. In this study, we are studying the treatment of upper-extremity spasticity.

You will receive the same treatment you would whether you decide to participate in this study or not. We are asking to collect data on some additional assessments of your response to the treatment you receive.

We will study the pain, range of motion and function in the arm before and after the procedures. We will also assess your satisfaction with the process. As many of our techniques are new it is extremely important to have scientific data supporting the results we are seeing. We can also use this to publish guidelines and seek funding as we are limited in how many we can do now without funding and space and support staff.

You are being asked if you are interested in participating in this study because you are being treated in this clinic. You have had a nerve block and are waiting for an intervention. You and your doctor have discussed the treatment options and have decided to proceed with the following treatment(s).

- Cryoneurotomy
- Radiofrequency Neurotomy
- Nerve surgery
- More extensive surgery with Muscle Lengthening, Joint release or fusion.

As part of your care, some people may be treated with more than one type of intervention. If this is the case, we are asking to measure your response to any of the treatments you receive.

This is a pilot study, meaning we may perform a longer larger study at a later date. After the procedure we will measure the range of motion in the arm and measure your ability to use the arm compared to before the procedure with one year of follow up.

WHAT PROCEDURES ARE BEING STUDIED?

Our current treatment of patients involves an assessment to see if their spasticity is being managed as best as possible, or are there are new procedures that could be offered to attempt to improve range of motion, improve function or reduce pain.

Patients that we feel could have more range of motion than they now have, undergo a diagnostic nerve block. You would have already gone through this procedure before entering the study. This involves an injection of local freezing with lidocaine (the type of injection for receiving stitches or dental work). This procedure is done with a nerve stimulator and an ultrasound machine for guidance. The freezing is injected through the skin. Patients that demonstrate a large change in range of motion or can move their limb better after nerve blocks in our clinic are offered several choices for further treatment. This includes:

1. A change in the botulinum toxin injection protocol. (For example, this could mean injecting different muscles or increased safe dosing of these muscles.) This option is not part of our study.
2. Receive a procedure called a neurotomy which involves a probe placed through the skin that will freeze (cryoneurotomy) or heat (pulsed radiofrequency) to the nerves to offer a long-lasting nerve block, from months to years.
3. Our surgeon may offer surgery on a small surgery to the individual nerve branches. In cases where the muscles are still contracted, surgery to release contracture may be offered. All procedures are explained in detail in the clinic before proceeding to the next step. Consent for all additional procedures is taken by the doctor providing the treatment, as is standard medical practice.

All procedures will be explained in depth and all options explored with patients and their families before choosing. Some patients may undergo a combination of the above procedures.

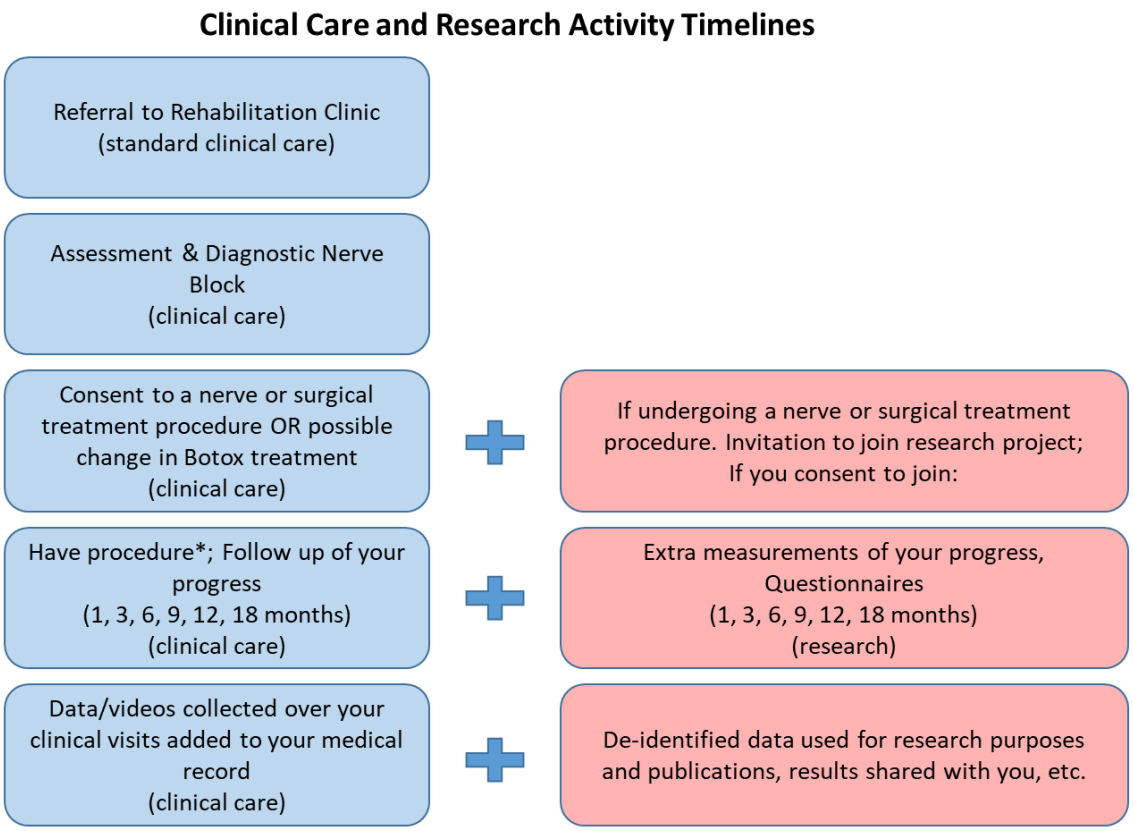
NUMBER OF PARTICIPANTS AND DURATION OF THE STUDY

A minimum of 50 participants will be included in this study, all assessed through our clinic at Victoria General Hospital. It is expected that patients enrolling in this study will participate for approximately 1.5 years.

STUDY PROCEDURES AND REQUIREMENTS

If you decide to participate in this study, you will have undergone a diagnostic nerve block in our clinic and a discussion of the possible treatment options.

VISUAL TIMELINE



*Note, you may have more than one type of procedure, based on your response/recovery. You and your doctor would discuss this as it is a clinical decision. (standard clinical care)

STUDY PROCEDURES

You will be contacted before you have your surgery or nerve ablation. Two to three weeks before the procedure, you would meet with our research assistant. There will be a series of measurements taken. The range of motion is measured before and after the procedure with both a measuring device, called a goniometer. All of these measurements are standard care.

Each patient will undergo a detailed assessment of their strength, range of motion and ability to use the arm and hand. These appointments will last up to one hour and involve both testing with our study team as well as filling out questionnaires. The assessments will occur at 1, 3, 6, 9, 12, 18 months. We will try to coordinate with your usual follow-up appointments with our clinic, which occur usually every three months.

LOCATION OF RESEARCH

The research will take place at Victoria General Hospital. All assessments will occur in the Rehabilitation Medicine Clinic.

The location and timing of your nerve or surgical procedure will not change if you are in the study.

You will be informed by your surgeon or anesthesiologist where the nerve or surgical procedure will occur.

WHAT IS REQUIRED IF I PARTICIPATE?

If you decide to participate in this study, you will undergo the same treatments as if you did not participate. The key difference is a longer assessment period with the research assistant to measure your abilities and use of your limbs before and after treatment. This means a longer appointment with the assistant before the procedure and assessments occurring at 1, 3, 6, 9,12 and 18 months after your procedure. Note this is the routine follow-up time you would be at our clinic. The appointments would last longer due to an extra hour for the measurements and questionnaires. This assessment process is only available to the study participants.

There will be no change in the care you receive from our clinic if you chose not to participate. Only the more detailed measurements and assessments will change.

RISKS

There are little expected risks associated with this study, as it involves measuring your movements, checking your grip and ability to move small blocks and fill out questionnaires.

This pilot study is evaluating the usual care offered in our clinic. There are no additional procedures offered to the study participants compared to the non-study participants.

BENEFITS

A promise or guarantee of benefit cannot be made. It is possible that you may indirectly benefit from study participation from the knowledge that doctors may gain about how we treat spasticity.

COMMERCIAL USE OF RESULTS

We do not plan for the commercialization of our results from this study.

ALTERNATE PROCEDURES

You may choose not to participate in this study. There is no change in the procedures available to you whether you participate or not.

COSTS TO PARTICIPANTS RESULTING FROM STUDY PARTICIPATION

There are no additional costs for study participants. The cost of surgery, and medical appointments are covered by your provincial health authority or your insurance company. As you are aware, medications such as botulinum toxin are subject to your family's deductible under Fair Pharmacare. Where applicable, your provincial health authority or insurance company will be billed for the standard tests, hospitalization charges, and any other tests that are considered the "standard of care" for your region.

DO I HAVE TO TAKE PART?

You are free to choose to participate or not. If you decide not to participate, your regular care or service will not be affected in any way. By consenting, you have not waived any rights to legal recourse connected to research-related harm. If you do decide to participate and then change your mind later, you can withdraw without any consequences or explanation. If you do withdraw from the study, we will ask you if we can still use your collected data.

If the data has already been analyzed, published, or anonymized (cannot be linked back to a person…the code linking numbers to names has been destroyed) removing data is not possible.

PAYMENTS TO PARTICIPANT FOR PARTICIPATING IN THE STUDY

You will not be compensated for participating in this study.

CONFLICT OF INTEREST STATEMENT

Dr. Winston has received speakers' honoraria and advisory board fees from Allergan, and Allergan has also funded conferences organized in part by Dr. Winston. Dr. Vincent has received educational grants from Allergan. Island Health has received funding in the past to provide education and services from Allergan. Allergan has provided unrestricted funding for this study with no expectation of receiving results or benefits from this study.

RESEARCHER'S RELATIONSHIP WITH PARTICIPANTS

As the researchers, we are the treating physicians for the participants. To help prevent our relationship from influencing your decision to participate, the following steps have been taken:

Our research assistant or clinic staff will provide you with the consent forms. Our research assistant will attempt to answer any questions you may have and forward them on to the physician leads. You may at any time wish to speak with the physicians about your involvement.

Please be aware that you will receive the same care and treatment whether you decide to join this study or not. For this study, we are asking to collect data on your medical outcomes, and to conduct some additional assessments.

NEW INFORMATION AND ON-GOING CONSENT

If new information becomes available, or if this project takes place over a longer period of time, we will ask you to renew your consent to participate.

This study involves our clinic's usual care. If any medical findings that were not expected are found during assessment and treatment, you will asked if you wish to be informed and findings would be discussed with your family doctor.

Sometimes a research project will recruit a subgroup of participants to perform other research activities. If this occurs, you will be provided with another consent form describing the new research activities and requesting your consent.

DISSEMINATION OF RESULTS

It is anticipated that the results of this study will be disseminated in the following ways:

This will include presentations as posters (many are seen in the clinic), medical journals publications, and lectures at conferences.

Upon completion of the study our findings will be shared with the study participants upon request and displayed in the clinic.

IN THE RESULT OF PHYSICAL INJURY RELATED TO THE STUDY

In case of questions, concerns or physical injury related to this study you can reach Dr. Winston or Dr. Krauss or Dr. Hashemi at 250-727-4221.

In the event that you suffer any injury caused by any procedure or technology required by the study protocol, you will receive all medical care required by your medical condition covered by your provincial health insurance plan. The study team will immediately assess the extent of injury.

We will have your case reviewed by an independent group of doctors outside the study from surgery, physiatry and anesthesia.

By signing this informed consent, you do not give up any of your rights. Moreover, you do not release the investigator and sponsor from their legal and professional responsibilities in case of a situation that has caused you prejudice or injury.

This study involves our clinic's usual care. If any medical findings that were not expected are found during assessment and treatment, you will immediately be informed and findings would be discussed with your family doctor.

We have established a Clinical Events Committee, of three physicians not involved in the study to review any safety events or concerns.

VOLUNTARY NATURE OF PARTICIPATION

Your participation in this study is voluntary. You may decline to participate by simply telling your study doctor. If you decide to participate and then later change your mind, you may withdraw from the study at any time without penalty or loss of benefits to which you may otherwise be entitled. Your decision will not in any way affect your future medical treatment or care.

The study team will remove your information from the study other than our hospital clinical record.

Your study doctor, the Research Ethics Board/ethics committee, the regulatory authorities, or the sponsor may terminate the study or your participation at any time with or without your consent.

This would only occur if you are unable to undergo the study procedures of the follow up for medical or personal reasons.

CONFIDENTIALITY

By agreeing to participate in this study, you permit the study team to collect and store de-identified information (information marked only with a coded number) with your study data. You will not be identified in any reports or publications in scientific journals on this study. Allergan, the sponsor, has funded this study as an investigator initiated trial. This means that we, the study team, have designed the study rather than Allergan. Allergan will not receive any study data.

All patients will be assigned a unique identifier, which will be used instead of your name on the data collection forms and database. The only demographics we will collect would be age, gender and type of illness. All data entries will be used with the identifier and not your name. We will not collect any other information about you from other sources. The patient identifier key will be in a locked cupboard in Rehabilitation Medicine Clinic.

Study data will be entered as soon as possible into a secure Research Database called REDCAP used by Island Health.

The change for each patient will be documented, as well as the overall change for the group.

The data is accessed by the treating doctors, as well as the research assistant, our therapists and the island health statistician. No one else is authorized to access this data.

The information we collect will be used is to produce research posters and papers for publication and presentation at conferences.

The Informed Consent Form (ICF) for the standard-care clinical collection. Patients can either sign it or have their legal representative consent to participation at the time of receiving.

AUTHORIZATION TO USE AND DISCLOSE YOUR PERSONAL HEALTH INFORMATION

The following information explains how your medical and health records and the research data collected about you for the study (“Protected Health Information” or “PHI”) may be used and disclosed. By agreeing to be in this study, you also give permission for the uses and disclosures of your protected health information as described below.

All personal information obtained, including your name, address, date of birth, medical history, clinical data and test results in relation to the study will be used for the purposes of research and medical education, as well as improving medical knowledge about spasticity including the treatment of your medical condition. Such information will be kept confidential and only authorized personnel will have access to it.

If you decide to participate in the study, you agree to allow your study doctor and the research staff to access and collect your personal data from you and/or your other healthcare providers and to use such personal data for the study. Your personal information (including name and date of birth) will be collected by and securely stored at the Rehab Medicine Clinic at Victoria General Hospital. This information may also be viewed by authorized personnel as required by law, review boards, and other persons who are required to watch over the safety and effectiveness of medical products and therapies and the conduct of research. If you were to pass away during the study, these parties may still have access to the information required for the study in order to verify it.

By signing this consent, you will permit your research staff to share de-identified data (all personal identifiers will be removed and you will be identified by a coded number specific to the study). Your de-identified information will be kept in computer files at Island Health for a period of time in the table below. Your results will be analyzed with data from other study participants like yourself, and may be disclosed to other hospitals or health professionals involved in or participating in the study (including their Research Ethics Boards), and as otherwise permitted or required by law.

Your data will be stored on Island Health Servers only.

DISPOSAL OF DATA

Your data from this study will be stored or disposed of in the following manner:

Data Source	How Destroyed	When Destroyed
Completed case data forms	Shredded	These will be retained for 7 years after study completion.
REDCAP Data Base	Retained on secure servers	As per Island Health REDCAP protocols

You may change your mind and revoke (take back) this permission to use your health information at any time. To cancel this permission, please call Dr. Winston at 250-727-4221

WHO SHOULD I CONTACT IF I HAVE QUESTIONS?

If you have further questions concerning this research, please contact:

Dr. Winston or Mahdis Hashemi at *250-727-4221.*

If you have any questions concerning your rights as a participant in this research, please contact Vancouver Island Health Authority Clinical Research Ethics Board at researchethics@viha.ca or 250-519-6726.

Measuring the efficacy of surgical and percutaneous neuroablative procedures, in the management of plateaued or refractory upper-extremity spasticity patients.

CONSENT OF PARTICIPANT

- I have read the information given above.
- I understand the meaning of this information.
- I have had the opportunity to ask my questions regarding the various aspects of the study and the Investigators and/or study coordinators have satisfactorily answered my questions.
- I also authorize the collection and disclosure of my personal information as outlined in this consent form
- I hereby consent to participate in the study.
- If a larger study is conducted based on this pilot study, we ask for your permission to use this pilot study data for the larger study
  Yes [ ] No [ ]

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care.

_____	_____
Participant's Name	Signature and Date
_____	_____
Legally Authorized Representatives Name	Signature and Date
_____	_____
Investigator/Delegate's Name	Signature and Date

The Vancouver Island Health Authority Clinical Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.