Evaluating the Efficacy of Obturator Cryoneurotomy for Hip Adductor Spasticity

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Participant Information and Consent Form

Evaluating the Efficacy of Obturator Cryoneurotomy for Hip Adductor Spasticity

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INVITATION

You are invited to participate in this research study due to your specific medical condition (lower limb spasticity); and because you have agreed to a procedure called cryoneurotomy. The study team is collecting data regarding the efficacy of this procedure in patients with spastic hip adductor muscles.

YOUR PARTICIPATION IS VOLUNTARY

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled, or are presently receiving. Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts. Please ask the investigators of the study to explain any words and/or phrases that are not clear to you.

If you wish to participate in this study, you will be asked to sign the form at the end. Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

WHO IS CONDUCTING THE STUDY?

The study is being conducted by Dr. Paul Winston at the multidisciplinary spasticity clinic at Victoria General Hospital (VGH). He will receive help from his study team. Dr. Winston's study team consists of two physiatrists, a physiotherapist, and a kinesiology student.

BACKGROUND

Spasticity which can be defined as an abnormal increase in muscle tone, is a common condition, and can cause many complications and interfere with daily function. The spasticity multidisciplinary clinic at Victoria General Hospital has provided multiple treatments for spasticity including medications such as botulinum toxin injections or oral medications and procedures such as cryoneurotomy, which involves application of a low temperature probe to a nerve under ultrasound guidance for patients with problematic spasticity. The aim of this study is to observe the functional effects of cryoneurotomy of the obturator nerve. This data will help us for better understanding of this procedure and its outcomes, which will consequently be used to improve future treatment options.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to investigate possible changes in spasticity degree, pain, function, and range of motion of targeted muscles, before and after cryoneurotomy, which is already planned for you as a part of spasticity treatment. These parameters will be measured at specific time periods; prior to procedure, 1 month after, and then every 3 months up to 1 year after cryoneurotomy, in your routine visit days. The results will be compared over time.

WHO CAN PARTICIPATE IN THIS STUDY?

You may be able to participate in this study if you are:

1) An individual who will have cryoneurotomy as a part of your standard treatment for hip adductor spasticity at the VGH spasticity multidisciplinary clinic.

2) aged twelve years or older.

3) Able to attend testing sessions, comply with testing protocols and provide written informed consent.

4) Able to understand and complete study-related questionnaires (must be able to understand and speak English or have access to an appropriate interpreter as judged by the investigator).

WHO CANNOT PARTICIPATE IN THE STUDY?

You cannot participate in this study if;

1) You have a history of previous nerve procedures such as chemical neurolysis with alcohol, cryoneurotomy, or surgery of the obturator nerve.

2)You have any other neurological pathology different from that responsible for the spasticity.

WHAT DOES THE STUDY INVOLVE?

Overview of the Study

The study will be conducted at the multidisciplinary spasticity clinic at Victoria General Hospital (VGH). All of parameters are a part of your normal care. The only extra measure is a 10-meter walk test.

Time Requirement

You will be asked to have an assessment before the cryoneurotomy procedure, and during your regular follow up appointments 1, 3, 6, 9 and 12 months after the procedure. This testing is a part of your routine physical examination, except for the 10-meter walk test which will last for approximately 5 minutes. During the testing session, both of your lower limbs will be tested.

If You Decide to Join this Study: Specific Procedures

Descriptions of the procedures you can expect are described below:

1.Completion of this informed consent form (only during the first session).

2 We will ask your permission to collect some of your demographic information such as your age, the cause of spasticity and the date of onset.

3.Clinical assessment: This is a part of your routine physical examination and includes hip passive and active range of motion, degree of spasticity of targeted muscles, observing and recording your normal gait. All of the videos that we record will be de-identified, meaning we will cover your face and any tattoos or other identifiable features in the recording. We will ask you to fill out a questionnaire to assess any related pain.

Also, prior to your procedure, you will be asked to make three functional goals. These goals will be revisited at each follow up.

4- The study team will observe your gait in a ten-meter walk test. In this test we will ask you to walk 10 meter in an unobstructed, flat hallway, as fast as possible. The study team will record the time.

*clinical assessment and 10 meter walking test will be done before the procedure and at 1,3,6,9 and 12 months after the procedure in your routine visit appointments.

WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS?

Every effort will be made to ensure your safety, privacy and comfort. All study procedures are non-invasive, meaning that no drugs will be administered, and no blood will be drawn. The study procedures will be performed by members of spasticity clinic who have been trained to do that. All Island Health PPE and COVID-19 protocols will be followed at all times. All staff and study participants will wear a mask at all times while in the clinic. All clinic staff have received two doses of a COVID-19 vaccine. All participants will be screened for COVID-19 symptoms upon entering the hospital, and again upon entering the clinic. All staff will complete a daily health check. All equipment will be disinfected after every use.

No harms or discomforts are anticipated as part of the assessments.

WHAT ARE THE POTENTIAL BENEFITS OF PARTICIPATING?

There is no direct benefit from your participation in the study; however, you and others may benefit from the knowledge generated from the study results.

WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

You will be informed in writing of any new information related to this study pertaining to your safety or anything that might influence your willingness to participate or continue. In this event you may be required to sign a new consent to indicate your willingness to continue to participate in the study.

WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, the study team will have a discussion with you about what will happen to the information that has already collected. You have the right to request the destruction of your information collected during the

study, or you may choose to leave the study and allow the investigators to keep the information already collected about you until that point.

If you choose to have the data collected about you destroyed, this request will be respected to the extent possible. Please note however that there may be exceptions where the information will not be able to be withdrawn for example where the information is no longer identifiable (meaning it cannot be linked in any way back to your identity) or where the data has been merged with other data. If you would like to request the withdrawal of your data, please let a study team member know.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator or his designate and by representatives of Island Health Research Ethics Board for the purpose of monitoring the research. Furthermore, funding agencies and academic journals may require the release of de-identified study data, upon completion of the study. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. Only this number will be used on any research-related information collected about you during the course of this study, so that your identity [i.e. your name or any other information that could identify you] as a participant in this study will be kept confidential. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Information that contains your identity will remain only with the Dr. Winston and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be released unless required by law. All study data is stored de-identified and stored in paper charts in a locked file cabinet at the spasticity clinic. De-identified data will also be stored in a secure, VIHA administered program called REDCap for the purposes of collection and analysis.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected and also given you the right of access to the information about you that has been provided to the sponsor and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to the Principal Investigator, Dr. Paul Winston.

WHAT HAPPENS IF SOMETHING GOES WRONG?

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and

professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

WHAT WILL THE STUDY COST ME?

There will be no additional costs due to participation in the study. Normal costs associated with a visit to the hospital, i.e., gas or parking, will still apply.

DISPOSAL OF DATA:

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

-All completed case data forms will be retained for 5 years after study completion and then will be shredded.

-All your data will be kept in REDCap database on VIHA secure servers and will be destroyed as per Island Health REDCap protocols.

WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY PARTICIPATION?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact the Principal Investigator, Dr. Paul Winston, via (250) 727-4221.

WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS ABOUT MY RIGHTS AS A RESEARCH SUBJECT?

If you have any concerns or complaints about your rights as a research subject and/or your experiences while participating in this study, contact Vancouver Island Health Authority Research Ethics board by e-mail at researchethics@viha.ca or by phone at 250-519-6726. Please reference the study number [H21-01646] when calling so the Complaint Line staff can better assist you.

AFTER THE STUDY IS FINISHED

Upon study completion, you will receive a comprehensive summary of your results, at your request.

PARTICIPANT CONSENT

Electrophysiological assessment of cryoneurotomy in spastic lower limbs

My signature on this consent form means:

- I have read and understood the subject information and consent form.
- I have had sufficient time to consider the information provided and to ask for advice if necessary.
- I have had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific objectives.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

_____	_____	_____
Subject's Signature	Printed Name	Date

_____	_____	_____	_____
Signature of Person Obtaining	Role	Printed name	Date

_____	_____	_____
Investigator's Signature	Printed Name	Date

My signature above signifies that the study has been reviewed with the study subject by me and/or by my delegated staff. My signature may have been added at a later date, as I may not have been present at the time the subject's signature was obtained.

Based on information collected during this study, you may be eligible to participate in future research studies at multidisciplinary spasticity clinic. Would you like us to contact you about future research studies in which you are eligible to participate? You would still have the option to decide whether or not you would like to participate.

_____	_____	_____
Subject's Signature	Printed Name	Date

_____	_____	_____	_____
Signature of Person Obtaining	Role	Printed name	Date

_____	_____	_____
Investigator's Signature	Printed Name	Date