FACULTY OF MEDICINE

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Participant Information and Consent Form

Electrophysiological assessment of cryoneurotomy in spastic lower limbs

Principal Investigator: Paul Winston, MD, PhD, FRCPC
Clinical Associate Professor, UBC
Victoria General Hospital
1 Hospital Way
Victoria, BC V8Z 6R5
Phone: (250) 727-4221

Study Contact Number: (250) 727-4221

INVITATION

You are being invited to participate in this research study because you are healthy individuals and the study team is investigating the results of a specific test (lower limb muscles responses to mild electrical impulses) in both healthy participants, and participants with lower limb spasticity who will undergo Cryoneurotomy (Application of ice to the selected nerves through a probe which is inserted percutaneously) to reduce spasticity in targeted 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 Principal Investigator Dr. Paul Winston at the multidisciplinary spasticity clinic at Victoria General Hospital (VGH), with help from members of the clinic. The team is conducting the study to figure out muscular-electrophysiological-parameter changes in both healthy controls and patients with lower limb spasticity.

BACKGROUND

Spasticity defined as an abnormal increase in muscle tone is a common condition that can cause many complications and interfere with daily function. The spasticity multidisciplinary clinic at Victoria General Hospital has provided multiple medication and non-medication treatments for spasticity, including 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 compare the results of persons who have had this treatment and healthy people. This data will enable us to have a 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 lower limb muscles' electrical conduction before and after cryoneurotomy, which is a part of spasticity treatment. To have a better understanding of possible changes, we will compare the results of patients with a healthy control group.

WHO CAN PARTICIPATE IN THIS STUDY?

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

1) A Healthy participant- with the age between 18 to 70. Over 70 will be excluded due to the expected natural alterations in electrophysiological parameters.

2) Able to attend and comply with the testing protocols.

3) Able to provide informed written consent.

4) Able to understand and speak English or have access to an appropriate interpreter.

WHO CANNOT PARTICIPATE IN THE STUDY?

You cannot participate in this study if you have:

1) A significant health problem that would lead to changes in muscle electrical conduction, including, but not limited to poorly controlled diabetes, lower limb fracture, pervious muscle/nerve surgery or any neurological disorders.

WHAT DOES THE STUDY INVOLVE?

Overview of the Study

The study will be conducted at the multidisciplinary spasticity clinic at Victoria General Hospital (VGH). You will be asked to participate in a brief test to measure your nerve electrical conduction. This will be done by applying a few brief electrical impulses and recording the response by a small surface recorder. Only the lower limb on your dominant side will be tested.

Time Requirement

You will be asked to attend a single testing session at the VGH electrodiagnosis department. The testing session will last for approximately 10 minutes.

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.

2. Nerve conduction study: you will be asked to undergo an electrical test called “nerve conduction study”. We will be performing nerve conduction studies in your lower limbs. For each test, sticker electrodes will be applied over your leg muscles. A small electrical stimulator will be applied over your nerve by one of the study examiners. Brief, small electrical impulses will be applied over your nerve. The stimulator will slowly be turned up until the examiner sees the best response (about 10 to 15 electrical impulses). The electrical impulses may cause your leg to twitch.

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.

During nerve conduction studies, you may feel some discomfort from the brief electrical impulses. As with any medical visit, you have the right to discontinue this testing at any time, if you perceive it to be too uncomfortable. There are no lasting effects from nerve conduction studies.

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 UBC Clinical Research Ethics Board or Island Health Research Ethics Board for the purpose of monitoring the research. Furthermore funding agencies and academic journals may require the release of study data, upon completion of the study. All information will be de-identified to release so, no information or records that disclose your identity will be published, nor will any information or records that disclose your identity will be released 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 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.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to insure 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 cost to you for participating in the study.

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 of 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 complains 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 [H20-02294] 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.

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PARTICIPANT CONSENT

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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