Evaluating the Efficacy of Obturator Cryoneurotomy for Hip Adductor Spasticity

NCT Number:
Date: September 10,2021

ADOLESCENT INFORMATION AND ASSENT FORM
Hip Adductor Cryoneurotomy

WHO IS IN CHARGE OF THE STUDY?

The doctor in charge of the study is **Dr. Paul Winston**. He is being helped by his research team. They will answer any questions I have about the study. If I am having an emergency and cannot talk to my parents or legal guardians, or if I am having any problems, I can call them at **250-727-4221** for help.

INVITATION

I am being invited to take part in this research study because I have hip adductor spasticity that my doctor has decided to treat with cryoneurotomy. Cryoneurotomy is a procedure for treating spasticity. A cold temperature probe is used to freeze an overactive nerve to let the muscle relax. The following pages explain the study so that I can decide if I want to take part or not. It is up to me if I want to be in this study. No one will make me be part of the study and no one will get mad at me if I don't want to be a part of this study.

DO I HAVE TO BE IN THIS STUDY?

I do not have to participate in this study if I don't want to. If I choose to participate, I can stop being in it at any time. The doctors and nurses will take care of me as they have in the past, regardless of whether I am in the study or not.

If I want to participate in this study, I will be asked to sign this form. My parent/guardian will need to sign a consent form before I am enrolled in the study, but I do not have to participate even if they sign the consent form. The researchers will not enroll me in the study unless I agree to do so.

I should take time to read the following information carefully and to talk it over with my family, and if I wish, my doctor, before I decide. I understand that I should feel free to talk to the study doctors if anything below is not clear. I can choose to be in the study, not be in the study, or take more time to decide. Even if I agree now to be part of the study, I can change my mind

later. I can ask the study doctor or study coordinator any questions I may have at any time during my study participation.

WHY ARE WE DOING THIS STUDY?

I have a condition called adductor spasticity that my doctor has chosen to treat with cryoneurotomy. My study doctors want to know more about the effects of this treatment. The study team will look at data from my tests and measurements to monitor how they are changing over time. If the study team can show that this works well, other physicians may want to use this treatment on their patients.

WHY ARE YOU INVITING ME TO BE IN THIS STUDY?

I am being invited to be in the study to test if cryoneurotomy will reduce the severity of my hip adductor spasticity.

WHAT WILL HAPPEN TO ME IN THIS STUDY?

If I choose to be in the study, I will come to the hospital only for my normal visits. During my visits, I will do all of my normal tests and measurements. I will be asked to complete a ten-metre walk test. I will be asked to complete a short questionnaire about my pain. A video will be recorded that shows how I walk. My face will not be in the video. There will be no extra trips to the hospital and the regular visits will still last about a half hour. If I choose to participate, the results of my tests over the next year will be used in the study.

CAN ANYTHING BAD HAPPEN?

There is nothing in this study that will have any negative effects on me. Steps are being taken to lower the chances of catching COVID-19 during my appointments. All clinic staff has received two doses of a COVID-19 vaccine. All clinic staff will wear a mask during my visit.

WHO WILL KNOW I AM IN THIS STUDY?

My privacy will be respected. The study team will not tell anybody else I am or have been a part of this study. They will not release any information that could be used to identify me unless they are required to do so by law.

To protect my privacy, the study team will remove any information that may be used to identify me from any study documents, and instead of my name appearing on them, I will be identified by a specific study code number that applies only to me. Only this code number will be used on

any research related information collected about me for this study so that my identity as part of the study will be kept completely private. Only Dr. Winston and his research assistants will have the ability to link this code number with my personal information, and the linking information will be kept in a locked cabinet in the Rehabilitation Medicine Department of Victoria General Hospital under the supervision and control of Dr. Winston.

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

If I have any questions or desire further information about this study before or during participation, or if I experience any side effects that were not outlined in this assent form, I can contact Dr. Winston at **250-727-4221**.

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

If I have any concerns or complaints about my rights as a research participant and/or experiences while participating in this study, I should contact the Island Health Research Ethics and Compliance Office by phone at 250-519-6726 or by emailing researchethics@viha.ca.

FUTURE STUDIES

There is a chance that during or after this study, the study team will find other questions needing answers that require future studies. If I am willing to hear about these future studies, I will mark the "yes" box. This does not mean that I will have to take part in a new study, just that the study team will let me know about it. If I do not want to be contacted about new studies, I will mark the "no" box.

Are you willing to be contacted by the researchers for future studies?

YES ☐

NO ☐

ASSENT TO PARTICIPATE

My signature on this assent form means:

- *I have read and understood this adolescent information and assent form.*
- *I have had enough time to consider the information provided and to ask for advice if necessary.*
- *I have had the opportunity to ask questions and have had acceptable answers 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 the quality of care that I receive.*
- *I understand that I can continue to ask questions, at any time, regarding my participation in the study.*
- *I understand that if I put my name at the end of this form, it means that I agree to be in this study.*

I will receive a signed copy of this assent form for my own records.

I agree to participate in this study.

_____	_____	_____
Participant's Signature	*Printed name*	*Date*

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