



SUBJECT INFORMATION AND CONSENT FORM

Prolotherapy in the treatment of supraspinatus tendinopathy

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Sponsor:	Grant from Work Safe BC

Emergency Contact: In case of an emergency. Dr. Helene Bertrand can be reached 24 hours a day, 7 days a week.

Introduction: You are being invited to take part in this research study because you have been diagnosed with tendinopathy of one of the tendons of the rotator cuff [shoulder] muscles.

Your participation is voluntary

Your participation is entirely voluntary, so it is up to you to decide whether or not to take part in this study. 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.

If you wish to participate, you will be asked to sign and date this consent form. If you do decide to take part in this study, you are still free to withdraw at any time and without giving any reasons for your decision.

If you do not wish to participate, you do not have to provide any reason for your decision not to participate nor will you lose the benefit of any medical care to which you are entitled or are presently receiving.

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 has received a grant from Work Safe BC. The Principal Investigator, Dr. Bertrand has received financial compensation from the funding agency Work Safe BC. for conducting this study (e.g., to pay the costs of equipment, procedures and staff). Dr. Bertrand does not receive any personal financial compensation for this study. You are entitled to request any details concerning this compensation from Dr. Bertrand.

Nature and purpose of the study

Rotator cuff tendinopathy tends to heal very poorly and very slowly. Standard therapy includes: in the acute phase, rest, ice, and nonsteroidal inflammatory medications (e.g. ASA, aspirin, Advil, Motrin, ibuprofen, Voltaren, Celebrex.) In the chronic phase: Exercise, physiotherapy, ultrasound therapy to dissolve calcifications and cortisone injections which can result in tendon rupture. Only 46% of those affected are free of pain and have full range of motion of their shoulder three years after the onset of

this condition. Prolotherapy involves injecting certain solutions into injured or diseased tendons (tissue that connects muscle to bone), ligaments (tissue that connects bone to bone or cartilage to bone) or joints (the point of connection between two bones or elements of a skeleton [especially if it allows motion]). These solutions cause inflammation (pain/swelling/heat/redness) and/or the release of growth hormones which cause these tissues to proliferate (re-grow and get stronger) and, therefore, to heal.

Though there are anecdotal reports of the success of prolotherapy, this has not been proven through a scientific evaluation of prolotherapy. The purpose of this study is to conduct an evaluation of the effectiveness of prolotherapy in ligament and tendon tears and laxity (looseness). The results from this study will be used to evaluate the effectiveness of using prolotherapy in the treatment of rotator cuff tendinopathy to help heal the tendon and to reduce pain and disability. The project will involve 75 people, 25 subjects who will receive prolotherapy (local anesthetic and a solution of 25% dextrose in the affected ligaments and tendons) and two groups of 25 controls each. One group will receive injections of local anesthetic but no dextrose in these same areas and one group will receive the same number and amount of local anesthetic injections but not at the sites likely to be effective. The controls will also be known as the placebo groups (in a controlled clinical trial, one group may be given a real medication while another group is given a placebo that looks just like it in order to learn if the differences observed are due to the medication or to the power of suggestion). This study will take about nine months to complete. There will be 5 visits at Dr. Bertrand's office, one x-ray of the shoulder, 2 ultrasounds of the shoulder and 3 assessments by the physiotherapist. All study participants will receive physiotherapy treatments every other week for three months. This study will take place at Dr. Helene Bertrand's office, 220 - 1942 Lonsdale Ave. North Vancouver, British Columbia, V7M 2K2. The entire study will take about 16 hours of your time.

Who can participate in the study?

You will be able to participate if you are age 19 to 74 years old and you have been diagnosed with tendinopathy of a rotator cuff tendon causing symptoms for at least three months.

Who should not participate in the study?

If you have an allergy to local anesthetic, or to corn from which the sugar solution is made, you cannot receive the treatment, as you are at risk for an allergic reaction.

If one of the tendons in your shoulder is completely torn instead of partially torn or frayed, you need surgery rather than prolotherapy, as prolotherapy involves re-growing tendon to make it stronger, but it cannot bridge a large gap between the ends of the tendon if it is completely severed.

If you are receiving prednisone or another corticosteroid, if you are on anti-rejection medications or if you are taking anti-inflammatory medication, prolotherapy will not work for you as the healing process which it triggers, is based partly on producing inflammation.

These are some of the reasons why you may not be able to participate. Dr. Bertrand will discuss these with you in detail.

Design of the study

You will be randomly assigned (like the flip of a coin) and have an equal chance of receiving any of the three possible treatments: prolotherapy or local anesthetic injections (modified prolotherapy), either in the ligaments and tendons of the shoulder, or away from these ligaments and tendons. (placebo group).

Neither you, the Radiologist, nor the physiotherapist will know which treatment you are receiving. Dr. Bertrand, who will be giving the injections, will only know if you are in the placebo group. This “blinding” is necessary to fairly test these therapies and to avoid bias (prejudice to the results). However this information is available in case of an emergency. The use of placebo groups as controls is necessary to provide a clearer assessment of the effectiveness of the treatment.

What does the study involve?

At your first visit, Dr. Bertrand will examine your shoulder, take a brief medical history and if you have not had an ultrasound of your shoulder, she will order one together with an x-ray of your shoulder, as this is part of standard care for people with tendinopathy of the shoulder. If the ultrasound shows tendinopathy or a partial tear of a rotator cuff (shoulder) muscle tendon, and the Xray does not show any osteoarthritis in your shoulder, Dr. Bertrand will refer you for a physiotherapy assessment, and telephone in a prescription for Tylenol number three which contains acetaminophen, caffeine, and codeine. If you are allergic to one of these you will receive another pain killer to take, such as tramadol (a narcotic, different from codeine) or Tramacet which contains acetaminophen and tramadol. She will also refer you to a physiotherapist who will assess how well, or how poorly, you can move and use your shoulder and will give you instructions on how to care for your shoulder and what exercises will help you.

At your second visit, you will return to Dr. Bertrand’s office where you will fill in a pain scale and be given a questionnaire with questions about what activities the injury interferes with. If there are questions on the questionnaire that you are not comfortable answering, you do not need to answer them. One hour before your appointment time, you will take two of the pain killer tablets you have been prescribed, as prolotherapy requires a set of six or more injections, and these can occasionally be painful. Once in Dr. Bertrand's office, you will be handed a sealed envelope with your identification number which will assign you to receive either prolotherapy or control injections. Before Dr. Bertrand administers the treatment to your shoulder, she will use a very fine needle (32 gauge needle) and inject

a local anesthetic around your shoulder area so your entire shoulder is almost pain free during your treatment.

She will then administer the treatment to your shoulder. After the therapy, you may wish to be accompanied home due to the pain and the medications which you have taken which may interfere with driving. Shoulder pain can persist for several days after the treatment. You will have enough prescribed painkillers to deal with the pain. **You must not take any anti-inflammatory medication such as aspirin, ibuprofen, Advil, Motrin, or other nonsteroidal inflammatory medications:** The aim of prolotherapy is to induce inflammation, as inflammation causes a release of growth factors which help healing. If you prevent inflammation, you inhibit this healing process. After your treatment, you will receive enough Tramacet or Tylenol number three for the next month, and you will be scheduled for your two physiotherapy sessions, 10 days and 25 days after your treatment. You will receive two more similar visits in Dr. Bertrand's office, one month and two months after your second visit. On your fifth visit to Dr. Bertrand's office, three months after your first treatment, you will again fill in a pain scale and be given a questionnaire with questions about what activities the injury interferes with, but this time you will not receive injections. If necessary you will receive more medications for pain. By then, the effects of the treatment should be complete. You will receive an appointment for a second physiotherapy assessment and, three months later, a last physiotherapy assessment and an ultrasound of your shoulder to see how well the frayed or torn tendon has healed. Nine months after your first treatment, someone will phone you to find out how you are doing.

What are the risks of prolotherapy to the shoulder?

The treatment itself can be painful and requires multiple injections. Following the treatment, you will have soreness in the shoulder which can last several days and, very rarely, up to two weeks. You might have an allergic reaction to the local anesthetic or the sugar water solution. If the needle hits a blood vessel you can have bruising in the area. If it hits a nerve, you can feel a brief, burning sensation down the limb. There are no major nerves in the areas that will be injected. Very rarely, some people have fainted as a reaction to being injected. If you are allergic to corn or to local anesthetic, you may have an allergic reaction to the injection solutions. You must not undergo prolotherapy using these solutions.

What are the benefits of participating in this study?

All study participants will receive physiotherapy assessments and treatments without cost. You may or may not personally benefit from the injections. Your participation in this study may also allow the investigators to gain more information about prolotherapy. If any significant new findings arise during the course of the research that relate to your treatment, you will be informed.

What are the alternatives to the study treatment?

You do not need to participate in this study to receive treatment for your condition. Some other treatment options for you may include rest, ice the affected area, use of anti-inflammatory medication(s), visits to the physiotherapist, exercise, ultrasound therapy and/or cortisone injections. You may choose one of these treatments rather than participate in this study. Your study doctor will discuss these alternatives with you.

What happens if I decide to withdraw from the study?

You may also stop participating in the study at any time you choose and you do not need to give any reason. It is your choice and all of your rights will still be respected. Your decision will not affect your further treatment or your relationship with your doctor. Your participation may also be stopped without your consent if your study doctor feels that it is in your best interest and you will be informed right away.

What happens if something goes wrong?

If you become injured or unexpectedly ill as a consequence of participation in the study due to the administration of the study therapy, your medical condition will be evaluated and medical care will be provided by one of the investigators or you will be referred for appropriate treatment. You will have access to Dr. Helene Bertrand cell phone number in case you need help.

Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else.

After the study is finished

You may not be able to receive the study treatment after your participation in the study is completed. There are several possible reasons for this, some of which include: The treatment may not turn out to be effective or safe. Your caregivers may not feel it is the best option for you. You may decide it is too expensive and insurance coverage may not be available.

What will the study cost me?

If you participate in this study, the study treatments, clinic visits and all procedures related to the study will be provided free of charge.

Will my taking part in this study be kept confidential?

Your confidentiality will be respected. No information that discloses your identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying you may be inspected in the presence of the Investigator or his or her designate by Health Canada, and the UBC Research Ethics Board for the purpose of monitoring the research. However, no records which identify you by name or initials will be allowed to leave the Investigators' offices.

If information from this study is presented publicly or published in a medical journal, you will not be identified by name or any other personally identifying information.

Who do I contact if I have any questions about the study during my participation?

You are encouraged to ask questions at any time during the study. In case you would experience side effects or have further questions about the study, please contact Dr. Bertrand

(for contact details see page 1).

If you have any concerns about your rights as a research subject and/or your experiences while participating in this study, contact the Research Subject Information Line in the University of British Columbia Office of Research Services by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598.

Subject consent to participate

I have read and understood the subject 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 result 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 understand that there is no guarantee that this study will provide any benefits to me. I have read this consent form and I freely consent to participate in this study. I have been told that I will receive a dated and signed copy of this consent form.

_____ /_____/_____
Signature of Subject Name (Printed) day month year

_____ /_____/_____
Signature of Investigator or Name (Printed) day month year
designated representative