CENTRE DE RECHERCHE | CHUS

RESEARCH INFORMATION AND CONSENT FORM

Study title: Characterization and temporal evaluation of the effects of subacromial cortisone injections and trans-cortical direct-current stimulation in the treatment of rotator cuff tendinopathy

Project number: 14-158

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IN CASE OF EMERGENCY OR FOR INFORMATION

From Monday through Friday, from 8am to 4pm, you can reach:

Dr. Samuel Larrivée	Tel : (819) 346-1110 ext. 14250
Marie-Philippe Turgeon	Tel: (819) 829-7131 ext. 45255
Dr. Frédéric Balg	Tél : (819) 346-1110 ext. 14233 ask the operator to call to call him on his pager
Mrs. Amy Svotelis,	Tel.: 819-346-1110, ext. 16194

Outside office hours, please go the nearest ER and mention your participation in a research study.

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We are asking for your participation in a research study, because you have been diagnosed with rotator cuff tendinopathy (shoulder tendinitis) and are eligible to receive a cortisone injection as a treatment. However, before you accept to participate, please take the time to read, understand and carefully consider the following information. If you accept to take part in this research study, you will have to sign the consent form at the end of this document and we will give you a signed copy for your own records.

In this Information and Consent Form you will find explanations about the goal of the study, its procedures, its risks and inconveniences, its advantages as well as the names of the people to reach if needed. This document may contain information or words that you do not understand. You should ask the study investigators or members of the study staff to answer your questions and explain any word or information you do not understand.

NATURE AND OBJECTIVES OF THE RESEARCH STUDY

Research data on the effectiveness of the treatment of rotator cuff tendinopathy is contradictory, especially concerning the efficacy and lasting effect of cortisone injections used to relieve the symptoms. Since the outcome of this treatment is also used in order to decide if there is an indication to perform a surgical procedure, it is essential to gather more reliable data on the efficacy of these injections as well as the efficacy of alternative new treatments for rotator cuff tendinopathy. Trans-cortical direct-current stimulation (tDCS) is one of these treatments. tDCS consists in applying electrodes on the scalp and stimulate the brain with a very weak current in order to modify the brain's activity and reduce pain.

This study's primary objective is thus to study the efficacy of cortisone injections and the efficacy of a new treatment to reduce pain, trans-cortical direct-current stimulation (tDCS), in patients suffering from rotator cuff tendinopathies.

STUDY PROCEDURES

If you accept to participate in the study, you will have to visit the clinic 4 times over a 5 weeks period. Each visit will last between 60 to 120 minutes. The visits will be located at research center of the CHUS Fleurimont and at the Research Center on Aging of the CSSS-IUGS. You will also receive questionnaires by mail on the 7th after the treatment.

Screening visit:

You will undergo several examinations and procedures that will determine if you are eligible to participate in the study. The study personnel will collect basic medical data and you will have to answer questionnaires that are enumerated below. You will then receive an inertial measurement unit, a small device the size of a watch used to detect the movement of your arm. You will also receive many copies of a short questionnaire to fill each day at home. You will not receive any injection at this point. This visit will last about 1 hour.

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First treatment visit:
One week after the screening visit, you will meet the physician, Dr. Balg, in order to receive a cortisone injection in your painful shoulder. Before the injection, you will be asked to fill questionnaires about your symptoms and the shoulder physical examination will be repeated. This visit will last about 1 hour.

Second treatment visit:
Two weeks after the injection, you will be asked to come to the clinic in order to assess the evolution of your symptoms.
We will assign you to a treatment group:

Group 1: cortisone injection alone
Group 2 : cortisone injection + trans-cranial direct current stimulation (tDCS) treatment

Group assignment will be randomly determined and will be established on the day of your visit. This visit will be divided in three parts and is unique to the research project. This visit is not usually included in the standard care of rotator cuff tendinopathy.

In the first part of visit
You will again have to fill questionnaires and will also receive a shoulder physical examination, as performed in the initial visit.

In the second part of the visit
A measurement of your brain excitability using trans-cortical magnetic stimulation (TMS) will be performed. TMS consists in stimulating a region of the brain using a magnetic field in order to elicit weak contractions of the shoulder muscles. This will give us information about the effect of your shoulder tendinopathy on the activity of your brain.

To do this, a trained technician will apply three electrodes on the skin of you shoulder. These electrodes will measure the contraction of your shoulder muscle. Then, using the TMS device, we will stimulate the zone responsible for the movement of your shoulder with a weak magnetic field many times to find the spot were the response to the stimulation is the strongest. We will then draw a dot on your scalp using a Sharpie pen to mark this point. Then, this spot will be stimulated many times to take different measures of you shoulder muscular contraction. This procedure is then repeated on the other shoulder and should last about sixty minutes in total. During the stimulations, you will feel a sensation resembling that of static shock. During the whole procedure, you will have to remain seating and move you head as little as possible.

For the third part of the visit
Depending on the group to which you have been assigned, you will either receive or not a 20 minutes treatment of tDCS. tDCS is a new intervention used, notably, in the treatment of chronic pain which consists in stimulating the brain using a weak electric current through the skull.

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To do this, a trained technician will disinfect the scalp where the electrodes will be applied using an alcohol swab. Two electrodes will then be placed on you head and over your eyebrow and fixed using rubber straps and adhesive tape. The electrodes will be soaked in water in order to improve the electric conductivity. Then, we will produce a weak electric current during 20 minutes. You will feel a sensation of tingling on your scalp for the first few minutes. During the whole duration of the treatment, we will ask you to stay seated, but you will be able to move on the chair and talk.

Once the tDCS ends, we will detach the electrodes and repeat the TMS measure on your painful shoulder in order to measure the change produced by the tDCS treatment.

If you are assigned to the group 1 (cortisone injection alone), the visit will last about 90 minutes. If you are assigned to the group 2 (cortisone injection and tDCS treatment), your visit will last about two hours. You can then leave the research center.

End-of-treatment visit:
Four weeks after the initial injection, you will be asked to come to the clinic for the end-of-treatment visit in order to assess the final evolution of your symptoms. This period is similar to the standard follow up of rotator cuff tendinopathy after a cortisone injection. Once again, you will be asked to answer questionnaires and will receive a shoulder physical examination. You will also meet Dr. Balg for a second time, who will discuss with you about the next steps in the treatment of you condition. This visit will last about one hour.

Mail follow-up
About 2 weeks after the last visit, you will an envelope with questionnaires to fill for the 7th week after the cortisone injection. Included will be daily questionnaires for seven days and questionnaires about the symptoms at your shoulder to fill on the last day of that week 7th week.

Procedures and examinations
Here is a description of the different tests and procedures that will be done during your participation in the study. **Please refer to the study schedule at the end of this document for a global vision of these interventions during the study.**

- Medical history
- Weight and height measurements
- Blood pressure measurement
- Questionnaire about your situation. Approximate time: 5 minutes
- Mood assessment questionnaire. Approximate time: 5 minutes
- Questionnaires about your symptoms. Approximate time: 20 minutes
- Short daily questionnaires. Approximate time: 1 minute
- Physical examination of both shoulders
- Trans-cortical direct current stimulation: new experimental treatment for chronic pain lasting about 20 minutes, which consists in stimulating a region of the brain

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using a weak electric current through the skull.

- Trans-cortical magnetic stimulation (TMS): procedure lasting about 60 minutes aiming at measuring the shoulder muscular contraction by stimulating a region of the brain using a magnetic field.

- Inertial measurement unit: you will have to wear the device during the day for all the duration of the study. The device must be taken off at night and during any activity that might involve a contact with water. It must also be recharged at night.

The study investigator and his staff will examine your medical records throughout the study.

Test, procedure and medical exam results done during this research study could appear in your medical record.

PARTICIPANT'S COOPERATION

- Do not participate in several research studies at the same time.
- Observe warnings about the use of other medications
- Inform research team of all other medications and natural products you may be using.

POSSIBLE RISKS ASSOCIATED WITH PARTICIPATION IN THE STUDY

Cortisone injection

As cortisone injections are part of the standard care of rotator cuff tendinopathy, this intervention does not bear any more risks than those of someone not participating in the study.

However, as a complement of information, here are listed the possible risks associated with cortisone injections in the shoulder:

- Vagal reaction (loss of consciousness) (10-20%);
- Burning sensation (13%);
- Temporary facial blushing (3-15%);
- Temporary pain after the injection (2-10%);
- Gastro-intestinal symptoms (5%);
- Severe pain (4%);
- Skin depigmentation (2-3%);
- Severe allergy (<1%);
- Steroid arthropathy (0.8%);
- Infection (0.001-0.072%);
- Impaired fasting glucose.

Trans-cortical direct current stimulation and neuro-physiological measures

Even if tDCS is a treatment and TMS is a measurement, both share the same risks as both stimulate brain cells from the scalp. Possible risks associated with these interventions are the following:

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- Convulsions (epilepsy) (rare);
- Temporary local pain (headaches, toothaches, neck pain);
- Temporary changes in hearing (TMS only).

The staff is specially trained to deliver these interventions. We will do everything to reduce the risks to a minimum. The staff is also trained to react quickly in case of an undesired event.

INCONVENIENCES ASSOCIATED WITH PARTICIPATION IN THE STUDY

Inconveniences linked with the participation in this research project include discomfort, shyness, anxiety, fatigue, stress and frustration linked to the experimentation, travelling, waiting, and time spent for research.

The daily wear of the inertial measurement unit and the daily questionnaires can also be considered a inconvenience for some participants.

TDCS is associated with a tingling sensation on the scalp which usually disappears after a few minutes. The sensation felt during the TMS stimulations resembles the sensation of a static shock. Being seated for a long time for these two interventions can also represent a source of discomfort.

BENEFITS RESULTING FROM YOUR PARTICIPATION IN THE RESEARCH STUDY

You may personally benefit from your participation in this research study, but it cannot be guaranteed. The additive use of trans-cortical direct current stimulation may enhance the response and duration of the cortisone injection used to treat the symptoms of your rotator cuff tendinopathy. The information resulting from this study will help increase our knowledge about the effectiveness of cortisone injections for the treatment of rotator cuff tendinopathy and the additive effect of trans-cortical direct current stimulation.

ALTERNATIVES TO YOUR PARTICIPATION IN THIS RESEARCH STUDY

You do not have to participate in this research study to be treated for your shoulder. You can meet an orthopaedic surgeon and still receive a cortisone injection if you decline to participate in this study.

VOLUNTARY PARTICIPATION TO AND WITHDRAWAL FROM RESEARCH STUDY

Your participation in this research study is voluntary. So, you are free to refuse to participate. You can also withdraw from the study at any time, without having to give any reason, by informing the study investigator or one of his assistants.

Your decision not to participate or to withdraw from the study will have no consequences on the quality of care and services you are entitled to or on your relationship with the investigator and other stakeholders.

During the course of this study, we will give you any new information that could affect your decision to keep on participating.

If you withdraw or are withdrawn from the study, your medical information already collected during the study will be kept as long as necessary to insure patient safety and to meet regulatory requirements.

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TERMINATION OF STUDY

The investigator in charge of the study or the research ethics board (REB) of the CHUS may end your participation in the study, without your consent, for the following reasons:

- New scientific developments show that it is in your best interest to terminate your participation;
- The study investigator responsible for the study thinks it is in your best interest;
- You do not follow the study instructions;
- There are administrative reasons to abandon the study.

CONFIDENTIALITY

While you take part in this research project, the study investigator and study staff will collect and record information about you in a research file. Only the information needed to meet the scientific objectives of the study will be collected.

This information could include data taken from your medical record concerning your past and present medical history, your lifestyle and results from tests, exams and procedures you will undergo during the study. Your file could also contain other information, such as your name, gender, date of birth and ethnic origin.

All the information collected during the study will be kept strictly confidential to the extent permitted by law. To protect your identity and privacy, you will be identified by a code number. The code key linking your identity and your research file will be kept safely by the study investigator.

The research data will be kept during 5 years by the investigator in charge.

The study data may be published in medical journals or shared with other persons during scientific meetings, but it will be impossible to identify participants. None of these publications or scientific communications will show information that could lead to your identification.

For monitoring and control purposes, your research and medical records could be inspected by a person mandated by the Research Ethics Board of the CHUS or the institution or by a person mandated by authorized public organisations. All of these people and organisations are bound by confidentiality policies.

For safety purposes, in order to be able to reach you quickly if needed, the study investigator will keep your name, surname, contact information and dates your participation in the study in a separate secured log, for one year after the end of the study.

You have the right to examine your study records in order to check the information collected about you and to correct it, if necessary, for as long as this information is available from the study investigator or the institution. However, some of this information may be made available to you only once the study has ended, in order to protect the scientific integrity of the study.

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POSSIBILITY OF BEING CONTACTED TO PARTICIPATE IN OTHER STUDIES

It is possible that the results obtained from this study give rise to other related studies. In this eventuality, it is possible that we contact you again to ask you if you want to participate in this new study. You are free to accept or decline without any consequences on your participation in this study or the treatment you are entitled to receive.

POSSIBILITY OF PHOTOGRAPHY

During the study, it is possible that pictures be taken in order to be used as visual aid in medical journals or during scientific meetings. Faces will be blurred. The pictures will be stored safely by the study investigator and no information identifying you will be kept. You are free to accept or decline without any consequences on your participation in this study or the treatment you are entitled to receive.

COMPENSATION

You will receive a global amount of 20 $ for each visit to compensate for expenses and inconveniences due to your participation in this research study.

PARTICIPANTS' RIGHTS AND INDEMNIFICATION IN CASE OF PREJUDICE

If you suffer any harm due to your participation in this research study, you will be provided with all the necessary care and services, at no cost to you.

By accepting to take part in this study, you do not waive any of your legal rights nor do you release the investigators, the sponsor or the institution where this research study is being conducted from their civil and professional responsibilities.

CONTACT PERSONS

If you have questions about your participation in this research study, please refer to the box on page 1.

For any question about your rights as a participant in this study or if you have comments or wish to file a complaint, you can contact the local Commissioner for Complaints and Quality Services of the CHUS at the following number: 819-346-1110, ext. 14525.

MONITORING OF ETHICAL ASPECTS OF THE STUDY

The Research Ethics Board of the CHUS approved this study and is in charge of its monitoring. Furthermore, we guarantee that any modification to the study protocol or to this information and consent form will be submitted to the REB's approval.

If you want to contact a member of the REB, please reach the REB's Support Services at the following number: 819-346-1110, ext. 12856.

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CONSENT

I declare having read this Information and Consent Form, especially where my participation and the associated risks are concerned. I declare that I received explanations about the study, that my questions were answered to my satisfaction and that I was given the time to think about it and make a decision.

I freely agree to participate in this research study.

☐ **YES** ☐ **NO**

I accept that my family physician be informed of my participation in this research study.

☐ **YES** ☐ **NO**

I accept to be contacted again about future studies.

☐ **YES** ☐ **NO**

I accept to be photographed, that my face will be blurred and that these pictures will be used in future communications and publications.

☐ **YES** ☐ **NO**

Name of participant *(block letters)*	Signature of the research participant	Date

Name of person who obtained consent *(block letters)*	Signature of person who obtained consent	Date

INVESTIGATOR'S COMMITMENT

I hereby certify that the provisions of this Information and Consent Form were fully explained to the participant, that his/her questions about the research study were answered and that the participant was clearly informed that he/she can withdraw from the study at any time, without any prejudice.

I am committed to honour what has been agreed upon in this Information and Consent Form and to give a signed copy thereof to the participant.

Name of investigator *(block letters)*	Signature of investigator	Date

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SCHEDULE OF STUDY VISITS AND PROCEDURES

# Visits	Pre-injection	Follow-up			Mail follow-up	
Treatment day	**Day -14 to -7**	**Day 1**	**Day 14**	**Day 28**	**Day 49-56**	**Day 56**
Tests/procedures						
Duration of visit (in hours)	2	1	0,5	1		
Consent	**X**					
Physical exam (including blood pressure, pulse, height, weight)	**X**					
Shoulder physical exam	**X**	**X**	**X**	**X**		
Questionnaire about life situation	**X**					
Mood assessment questionnaire	**X**					
Questionnaires the shoulder symptoms	**X**	**X**	**X**	**X**		**X**
Meetings with the physician		**X**		**X**		
Shoulder injection		**X**				
Trans-cortical magnetic stimulation			**X**			
Trans-cortical direct current stimulation			**X**			
Side effect monitoring		**X**	**X**	**X**		
Inertial measurement unit wear	**All time, during the day**					
Mini-questionnaires	**Every day**				**7 days**	

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