



CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY FOR HEALTHY PATIENT WITH NO CHRONIC PAIN

Study Title:

Evaluation of Motor Unit Abnormalities after Experimentally Induced Sensitization Using Capsaicin: A Randomized, Double-Blinded, Placebo-Controlled Study

Investigator/Study Doctor:

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Introduction:

You are being asked to take part in a research study. Please read the information about the study presented in this form. The form includes details on study's risks and benefits that you should know before you decide if you would like to take part. You should take as much time as you need to make your decision. You should ask the study doctor or study staff to explain anything that you do not understand and make sure that all of your questions have been answered before signing this consent form. Before you make your decision, feel free to talk about this study with anyone you wish including your friends, family, and family doctor. Participation in this study is voluntary.

Background/Purpose:

Myofascial pain syndrome (MPS) is a prevalent chronic pain disorder primarily characterized by myofascial trigger points (MTrP). Myofascial trigger points are stiff, taut bands of muscle distinguished by hypersensitivity. Central sensitization has been proposed as the primary mechanism underlying trigger point development. Central sensitization is associated with hyperexcitability of neuronal responses to normal or noxious stimuli. The goal of this study is to determine whether sensitizing healthy muscle using capsaicin induces a change in texture features from Ultrasound pictures and motor unit frequency and amplitudes from Electromyography. Central sensitization will be induced using topical capsaicin (delivered in a cream) at two different concentrations. The placebo-controlled variable will be a skin cream that does not contain capsaicin. Multichannel surface electromyography (EMG) and intramuscular EMG will be recorded. The EMG signals will be decomposed into individual motor units. Firing rates, shapes, and amplitudes of motor units will be tracked over the entire EMG signal. When the muscular characteristics of inducing central sensitization are known, comparisons can be made to the muscular characteristics of trigger points or other

unknown phenomena. This study could be the foundation to determine if central sensitization is a direct cause of trigger point development and provides a basis for future work in this field.

Study Visits and Procedures:

If you participate in this study, you will be seated upright with your hands on your lap. At this time, ultrasound pictures will be taken of your trapezius and infraspinatus muscle. Surface electromyography and intramuscular electromyography will then be acquired during an exercise. Following this, a topical cream (capsaicin cream or a placebo cream) will be applied onto your trapezius muscle. A 20-minute wait period will follow in order to induce the effects of capsaicin. Central sensitization at this time will be assessed using brush allodynia. Brush allodynia is a standard clinical procedure that involves testing for evoked pain by brushing a region on the subject's skin. Once central sensitization is obtained, you will be asked to gently contract your trapezius muscle. Surface and intramuscular recordings will be acquired again during the same exercises as previously. The intramuscular needle will then be removed and participants will be bandaged and cared for appropriately by the physician performing the experiment. Lastly, post-treatment ultrasound pictures will be taken again. You will be re-examined to determine if there were any adverse effects from the experimental procedures. If any occurred, then these will be carefully managed by the medical members of the research team and recorded. You will be asked to remain at the lab for an additional 10 minutes to ensure you are well prior to leaving.

Risks:

Risks to the subjects can include warmth, stinging or burning on the site of application. The region of capsaicin application can experience redness or dermatitis.

In the unlikely event that you are allergic to capsaicin, a medical doctor will administer the correct treatment. You will be in the outpatient clinic at Toronto Rehabilitation Institute and will be quickly cared for.

- A doctor will be administering the dosage of capsaicin and monitoring the region, and your vital signs to identify any adverse effects.

If you smell the capsaicin cream, coughing or throat irritation could occur. You will be advised not to put your face anywhere near the site of application.

Benefits:

You may or may not receive any direct benefit from participating in this study. Health professionals may gain knowledge about how to measure pain sensitivity, and markers of central sensitization. You may gain knowledge about the pain processing pathways and systems within your body.

This study will enhance the understanding of mechanisms responsible for central sensitization and its consequences on the neuromuscular system. It could give more insight on if central sensitization effects muscular recruitment and structure. This information can direct future treatment for pain patients or direct future research on determining how myofascial pain is developed.

Confidentiality:

If you agree to join this study, the study doctor and his/her study team will look at your personal health information and collect only the information they need for the study. Personal health information is any information that could be used to identify you and includes your:

- name,
- date of birth,
- new or existing medical records, that includes types, dates and results of medical tests or procedures.

The information that is collected for the study will be kept in a secure and confidential location for 10 years. A list linking your study number with your name will be kept by the study doctor in a secure place, separate from your study file. Only the study team or the people or groups listed below will be allowed to look at your records.

On publication of your data, your identity will be anonymized and no personal identifiers will be provided.

Research Information in Shared Clinical Records:

If you participate in this study, information about you from this research project may be stored in your hospital file and in the UHN computer system. The UHN shares the patient information stored on its computers with other hospitals and health care providers in Ontario so they can access the information if it is needed for your clinical care. The study team can tell you what information about you will be stored electronically and may be shared outside of the UHN. If you have any concerns about this, or have any questions, please contact the UHN Privacy Office at 416-340-4800 X6937 or email at privacy@uhn.ca.

Representatives of the University Health Network Research Ethics Board may look at the study records and at your personal health information to check that the information collected for the study is correct and to make sure the study followed proper laws and guidelines.

All information collected during this study, including your personal health information, will be kept confidential and will not be shared with anyone outside the study unless required by law. You will not be named in any reports, publications, or presentations that may come from this study.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission.

Voluntary Participation:

Your participation in this study is voluntary. You may decide not to be in this study, or to be in the study now and then change your mind later. You may leave the study at any time. You may also withdraw your data prior to publication. We will give you new information that is learned during the study that might affect your decision to stay in the study.

Withdrawal from the Study:

You may withdraw from the study at any time. Your personal information will be destroyed in a confidential manner.

Costs and Reimbursement: There will be no cost for participating in the study. You will not be reimbursed for taking part of the study.

Rights as a Participant:

If you are harmed as a direct result of taking part in this study, all necessary medical treatment will be made available to you at no cost.

By signing this form you do not give up any of your legal rights against the investigators, or involved institutions for compensation, nor does this form relieve the investigators, sponsor or involved institutions of their legal and professional responsibilities.

Conflict of Interest: Researchers have an interest in completing this study. Their interests should not influence your decision to participate in this study.

Questions about the Study:

If you have any questions, concerns or would like to speak to the study team for any reason, please call: 416- 597-3422 X4612. If you wish to contact a research team member by email you may do so using: dinesh.kumbhare@uhn.ca but please note that the security of e-mail messages are not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. E-mail should not be used to discuss information that is considered sensitive or in an emergency situation since e-mail may be delayed. The research team member will discuss any sensitive matter by telephone not email.

If you have any questions about your rights as a research participant or have concerns about this study, call the Chair of the University Health Network Research Ethics Board (UHN REB) or the Research Ethics office number at 416-581-7849. The REB is a group of people who oversee the ethical conduct of research studies. The UHN REB is not part of the study team. Everything that you discuss will be kept confidential. You will be given a signed copy of this consent form.

Consent:

This study has been explained to me and any questions I had have been answered. I know that I may leave the study at any time. I agree to the use of my information as described in this form. I agree to take part in this study.

Print Study Participant's Name

Signature

Date

My signature means that I have explained the study to the participant named above. I have answered all questions.

Print Name of Person Obtaining Consent

Signature

Date

Was the participant assisted during the consent process? ☐ YES ☐ NO

If **YES**, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter for the participant during the consent process and attests that the study as set out in this form was accurately interpreted and has had any questions answered.

Print Name of Interpreter

Signature

Date

Relationship to Participant

Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to, and has had any questions answered.

Print Name of Witness

Signature

Date

Relationship to Participant