# INFORMED CONSENT FORM

**Identifiers: NCT03636386**

**Protocol ID: 60312069**

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**Brief Title: Percutaneous Microelectrolysis on Myofascial Trigger Points Pain. (MEP)**

**Official Title: Effectiveness of Percutaneous Microelectrolysis in the Decrease of Pain in Myofascial Trigger Points: Evaluation Through Algometry and Visual Analog Scale. Randomized Controlled Trial.**

# ANNEX 1. DATA COLLECTION PROTOCOL

# INFORMATION FOR PATIENTS

## Study name and the Principal Investigator

You are being invited to participate in the study **Effectiveness of percutaneous microelectrolysis in reducing myofascial trigger points pain: assessment through Algometry and Analog Visual Scale. Randomized controlled trial.**

**Principal researcher: Hernán Andrés de la Barra Ortiz**

## Introduction.

Electrical stimulation has a wide range of clinical applications in rehabilitation, being used for activities such as strengthening, pain control, edema management, or inflammation control after an injury or surgery. One of most classic forms of electrotherapy is the is direct current, which stands out for its effects and that are not achieved with other modalities of electrical stimulation. A new therapeutic alternative through this current is the procedure called Percutaneous Microelectrolysis (MEP®) which has begun to have a boom in Latin America a couple of years ago. MEP® is a minimally invasive procedure in which a Low Current Direct Current is used.

Myofascial Trigger Points (MTrPs) are a common source of regional musculoskeletal pain with a prevalence of 85% in the population. They are characterized by tight bands of skeletal muscles, being painful to compression, and can also generate patterns of referred pain, hypersensitivity to pressure, among other discomforts. This research will focus on studying the effectiveness of MEP as an analgesic intervention in MTrPs. It is interesting to initiate research in the field of direct current in order to demonstrate the potential analgesic benefits achieved through polar effects through the MEP® technique.

## Objective.

Assess effectiveness of MEP technique in reducing the pain pressure threshold (PPT) and pain intensity in myofascial trigger points (MTrPs).

## Who can participate in this study?

Subjects with an age over 18 years, without pathologies or clinical conditions in cervical region or upper limb shoulders, with presence of hypersensitive painful points in upper trapezius muscle and that do not present apprehension or fear to electrostimulation.

## Study Procedure

Study will be divided into 3 stages; 1. Sampling phase, 2. Evaluation phase and 3. Intervention phase. The first stage will be carried out through a questionnaire that will allow researchers to choose potential participants. If you are reading this consent it means that you have successfully approved this stage and that you meet the characteristics necessary to participate in the study. Second stage contemplates an evaluation through pressure algometry to determine the presence of hypersensitive painful points in upper trapezius muscle and explanation of the electrical procedure that will be used in investigation. Evaluation procedure will be governed by same physical and technical conditions that will be applied in the experiment stage. To access second stage, you must agree expressing your willingness to participate through the consent you are reading. To enter phase 3, you must present a sensitive point in the upper trapezius muscle registered by the researchers in phase 2. You will have immediate knowledge in phase 2 regarding whether you can proceed to the final phase (Phase 3 or intervention) depending on Present or not sensitive points in the muscles described. Phase 3 consists of the algometric measurement and pain intensity when evaluating the pressure on the hypersensitive trigger point. This will be continued immediately by treatment for said sensitive point. Algometry record is minimally painful or uncomfortable and painful intensity record is non-invasive using a visual scale. Regardless of group to which you are appointed, indicate that treatments applied will be in your benefit so that it will help you reduce or eliminate discomfort of sensitive points investigated in the evaluation of phase 2. All interventions will be performed by a professional with clinical experience, who also teaches physiotherapy course of the Kinesiology degree.

Written record is hereby given by this consent, that you are free to leave the study at the stage you want, and that the investigators will not force you to complete it, nor will it bother you demanding the reasons for dropping out.

## Risks and benefits

There are no risks because it will work under strict safety standards following the recommendations of literature for work with this modality of electrotherapy. In minimal cases, a slight redness may remain in the current application area, which will disappear in a few minutes. This is due to the increase in local circulation. As potential benefits of the study, it can be assessed whether percutaneous microelectrolysis technique is effective in reducing the threshold of painful pressure and pain intensity in myofascial trigger points, highlighting it as another treatment alternative to those already existing.

## Compensation for damages or complications

There are no complications or compensation for damages in this investigation.

## Who designed the study?

Design and intellectual property of study is from Hernán Andrés de la Barra Ortiz professor, Andrés Bello University, who will have the role of principal investigator.

## Costs

There is no cost to you when you are part of this investigation.

## Voluntary participation

Your participation in this study is completely voluntary. You can refuse your participation at any stage of the study and withdraw your consent at any time.

## Confidentiality

All information generated during the study will be anonymized, that is, with codes without revealing personal data, and handled confidentially. Only the principal investigator will have access to it, who will keep all data safe. This is a measure of verification that the investigation is being carried out in accordance with what is described in the protocol, and in accordance with the ethical guidelines and laws that regulate the execution with research in human beings.

## More information

**Principal researcher: Hernán Andrés de la Barra Ortiz.**

**Approval: 28 June 2018, Ethics Committee Eastern Health Service (Salvador Hospital), Santiago de Chile.**

**Project: Effectiveness of percutaneous microelectrolysis in reducing myofascial trigger points pain: assessment through Algometry and Analog Visual Scale. Randomized controlled trial.**

## INFORMED CONSENT SHEET

**Recognition of the Participant (or his Representative) in the investigation:**

• I have read and understood the information written in this Informed Consent form of the research project called **Effectiveness of percutaneous microelectrolysis in reducing myofascial trigger points pain: assessment through Algometry and Analog Visual Scale. Randomized controlled trial.**

• I have had the opportunity to ask questions regarding this research which have been answered satisfactorily.

• I understand that I will receive a signed copy and date of this CI form.

• I consent to the use and disclosure of the study information as described in this form. Sensitive information will be used strictly confidentially and for no other purpose outside of this study without my consent.

• I understand that I may withdraw and refuse my participation in this study at any time without altering my health care in this institution, without penalty or loss of benefits to which in other circumstances I would be entitled.

• I freely agree to participate in this research project.

• I voluntarily sign this consent form.

**Participant Name or Participant Representative:** _____

**Participant or Representative Signature:** _____ **Date:** _____

Investigator Statement:

The undersigned declares that he has fully and carefully explained the nature, purpose, risks and benefits of this investigation to the participant or his Representative who is signing this consent form and has answered the questions and doubts satisfactorily.

**Name of the researcher who takes CI:** _____

**Signature of the researcher:** _____ **Date:** _____