Official Title of the study: “COMPARATIVE EFFECT OF PERCUTANEOUS MICROELECTROLYSIS WITH OR NO CURRENT EMISSION IN THE TREATMENT OF CERVICAL PAIN IN MYOFASCIAL TRIGGER POINTS OF THE TRAPEZE”

APPROVED BY THE ETHICS COMMITTEE: November 2019

Document Date: August 2022

PATIENT INFORMATION SHEET

You are being invited to participate in a research project called “COMPARATIVE EFFECT OF PERCUTANEOUS MICROELECTROLYSIS WITH OR NO CURRENT EMISSION IN THE TREATMENT OF CERVICAL PAIN IN MYOFASCIAL TRIGGER POINTS OF THE TRAPEZE” that develops in the Extension Research, Extension and Training Center of the National University of Córdoba and coordinated by Arguello Retamar, Verónica Inés.
Before signing your consent it is important that you carefully read and understand the detailed information about this study. You can ask all the questions want or request an explanation of words you do not understand.
The data will be used for an investigation whose objective is: To analyze the effect of MEP as a technique for treating pain in the Myofascial Trigger Point (MTP) of the muscle trapezius compared with acupuncture application and evaluate the effect of two protocols of treatment in relation to its function, pain and strength in muscle trigger points, Determining the ranges of joint mobility before and after each treatment.

We are requesting your authorization to: conduct research on treatment protocols that will take place over 3 weeks, with one session per week. The evaluation that will be carried out will be: you must identify a number through the visual analog scale (you will say a number of current pain; where zero is no pain and ten is the maximum pain experienced), measurement of force with a dynamometer (a device is placed in a specific area of the muscle that will highlight a number to identify the current pain) and mobility with the goniometer (the number and degrees of mobility of the head and neck is identified with an instrument), and everything will be recorded on a card registration and photography. The score will be recorded in a validated neck pain questionnaire called Northwick Park neck pain questionnaire (it is a questionnaire that is organized by sections of 5 items, each with reference to the intensity of pain, duration of symptoms and activities of daily living that could be affected by neck pain). Subsequently, a protocol of 2 treatments will be carried out (previously selected by envelope), which is carried out with a device that uses an acupuncture needle connected to the aforementioned device for treatment. At the end, 3 (three) specific trapezius elongations will be executed. Times procedure will take approximately 1 hour per session.

The correct behavior in research is to inform the participant that the results will be available for attention at the Research, Extension and Training Center, in addition to the possibility of being presented in scientific journals and National and International Congresses.

Expected risks and inconveniences: the application of an acupuncture needle with or without current implies an inconvenience in the placement of it, and may generate a momentary and passing inconvenience. Post treatment can maintain discomfort or local scarring of the size of the acupuncture needle placement, all of the above will pass over the course of days in reference to local regeneration times.

Benefits and compensation: You will not receive any remuneration or benefit for participating from the researchers and/or other institutions associated with the research. You can withdraw from the study or discontinue your participation at any time without explanation. Your refusal to participate will not cause you any prejudice. The participant may withdraw until the inclusion of their data in the global results, where they can no longer be individualized.
By signing the informed consent, you do not waive any of the rights that correspond to you under the laws of our country. The results may be published or presented at conferences but no personal data or photographs that can identify you will be included. Law 25326 on the protection of personal data safeguards your personal information. Your background record will be identified by a code and not by the use of your name and will only be used for the purposes mentioned in this study.

If you have questions as a subject participating in a research, you can contact the Health Research Ethics Committee that has approved this study at the Hospital Nacional de Clínicas, coordinator Dr. Susana Vanoni, Monday through Friday from 08:00 to 15:00, Santa Rosa 1564 , B° Clinics, Tel 4337014 – Int 188.
For inquiries related to the research design, you can contact the research team: Lic. Arguello Retamar, Verónica Inés, Monday-Wednesday-Friday from 8 a.m. to 12 p.m., Center for Research, Extension and Training at the School of Kinesiology and Physiotherapy of the National University of Córdoba with address at Avenida Enrique Barros s/n Ciudad Universitaria.

PARTICIPANT / PATIENT
SIGNATURE:……
CLARIFICATION:……
DNI:……...
DATE:……

INVESTIGATOR:
SIGNATURE:……..
CLARIFICATION: ARGUELLO RETAMAR, VERÓNICA INÉS
DNI: 33,982,505
DATE:……

INFORMED CONSENT FORM

By signing freely and voluntarily, I express my consent to participate in an investigation entitled "COMPARATIVE EFFECT OF PERCUTANEOUS MICROELECTROLYSIS WITH OR WITHOUT CURRENT EMISSION IN THE TREATMENT OF CERVICAL PAIN IN MYOFASCIAL TRIGGER POINTS OF THE TRAPEZE" that has been clearly explained to me. I have read and understood the information sheet and have had the opportunity to ask questions and am satisfied with the information received. I have been informed by an investigator whose name and surname appear at the bottom of this document.

I am aware that my participation is free and voluntary and that I can withdraw without prejudice. I have been informed that the data derived from this study can only be deleted from the database until they are integrated and published anonymously, where there will be no way to delete them.
I accept the performance of the different procedures involved.
I understand that I will not receive compensation for participation or other benefits. The investigation will not generate expenses for me either.
The results may be presented at scientific meetings or published in specialized journals, always keeping personal data confidential.

PARTICIPANT / PATIENT
SIGNATURE:……
CLARIFICATION:……
DNI:……...
DATE:……

INVESTIGATOR WHO OBTAINED CONSENT:
SIGNATURE:……..
CLARIFICATION: ARGUELLO RETAMAR, VERÓNICA INÉS
DNI: 33,982,505
DATE:……
