Prediction of response to manual physiotherapy using somatosensory profiles in patients with cervicobrachialgia.

PRINCIPAL INVESTIGATOR: Xabat Casado Zumeta

22.09.2023

PATIENT INFORMATION LEAFLET

Deusto
Universidad de Deusto
Deustuko Unibertsitatea
University of Deusto

CENTRE: University of Deusto. University of Deusto.

STUDY TITLE: Prediction of response to manual physiotherapy using somatosensory profiles in patients with cervicobrachialgia.

PRINCIPAL INVESTIGATOR: Xabat Casado Zumeta

You have been invited to participate in this study:

Our intention is to provide you with **sufficient information** so that you can evaluate and judge whether or not you want to participate in the study. To do this, it is advisable to read this leaflet carefully and ask any questions you may have regarding the study.

For this reason**, we request your consent** to participate in the study described below**,** which has been approved by the Ethics Committee for Research with Medicines of the Basque Country and respects current regulations.

STUDY OVERVIEW

The present study aims to recruit patients who have cervicobrachial pain and evaluate the effectiveness of a manual physiotherapy treatment commonly used in clinical practice, with the aim of knowing if there are certain characteristics that make a group of patients improve more than the rest. The manual physiotherapy treatment you will receive consists of techniques that aim to mobilize the anatomical structures around the neck along with home exercises to move the neck and the nerves involved. This will be the only treatment you will receive if you decide to participate in the study. The different sensory measurements on the pain threshold and the tests of the clinical examination aim to explore mechanisms of the nervous system that allow us to make a classification by groups, based on what was found in the examinations.

The possible changes that this treatment causes in different sensory parameters (thermal pain threshold, vibration and pressure) will be evaluated. Likewise, the possible changes that the treatment causes in sensation, strength or reflexes will be studied. As well as in the mobility of the neck and arm through the tests that we will perform.

We also request permission to access the results of the nuclear magnetic resonance and x-rays performed for the diagnosis of your cervicobrachial pain.

No invasive testing or drug treatment will be performed. It does not pose any additional risk to the patient.

Voluntary participation

Participation in this study is **completely voluntary,** and the decision not to participate will not affect your relationship with the team of traumatologists and physiotherapists who treat you or imply any prejudice in your treatment. Participation in the study is free of charge and does not entail any additional financial burden. You have the right to decide on the fate of your data.

What does it mean to participate in this study?

Participation in the study implies that you commit to the investigator to comply with the instructions of the study protocol.

What are the drawbacks of participating in the study?

Participating in the study will mean going 7 times to the Larramendi building on the Donostia campus of the University of Deusto for evaluation and subsequent treatment. Various materials will be used for hand, arm and neck measurements. They are measurements in which we will evaluate your ability to modulate pain, so we will apply different thermal, vibration and pressure stimuli to know their pain threshold to them. They are totally safe methods that allow you to stop the stimulus immediately with a button. That is, you can decide when to stop the measurement voluntarily. The manual physiotherapy treatment applied will be carried out based on your irritability and pain, so the techniques applied may be slightly annoying, but they will be adapted to your situation to avoid adverse effects as much as possible. However, the possible risks and inconveniences that may arise from the treatment applied will be covered by an insurance policy.

In the first visit you must fill out a form with your personal data and then we will perform the sensory exams. **In these tests we do not intend to evaluate your pain tolerance, what we seek is to know your pain onset threshold, so you will voluntarily stop the measurement when it starts to be annoying.** This measurement is usually performed in clinical practice in order to know the irritability of your symptoms. A metal

bucket will be placed in the area of pain and you must indicate when the temperature of the bucket begins to be annoying due to cold or heat**.** We estimate that this measurement will last 20 minutes. Then, using a device that is capable of recording the pressure we make, we will make a progressive pressure in your area of pain until you indicate when it becomes annoying. This measurement will take about 5 minutes.

The next test involves placing your hand in cold water (10ºC) and holding it for 30 seconds. This test is intended to produce a tolerable discomfort for you, so the temperature can be regulated depending on your situation. While keeping your hand in the water, we will perform the same pressure measurements made earlier in triplicate. This test will be done in about 15 minutes. Finally, we will apply by means of a pen with a calibrated filament a stimulus of slight puncture that in no case will pierce the skin. We will ask you to tell us if the repetition of this stimulus increases your symptoms, which will not take us more than 10 minutes.

Once finished with the sensory examination, we will perform the clinical examination. In it, we will perform techniques and methods of exploration commonly used in clinical practice. Using a cotton ball, we will lightly touch several areas of your arm to know if you have any alteration of sensitivity. We will perform manual tests to know if you have any loss of strength and evaluate the reflexes of the arm with an exploration hammer. These techniques do not produce any discomfort and we will carry them out in approximately 20 minutes. Next we will examine your neck and arm. We will assess your degree of mobility and apply common screening techniques that can reproduce your symptoms. The onset of symptoms will be noted and the test will be stopped, so you can decide voluntarily.

Finally, we will ask you to complete questionnaires that aim to obtain information about your status. Our forecast is that you can fill them in 15-20 minutes.

What benefits can I get by participating in this study?

At the time of participating in the study, you will receive the treatment that has shown the most evidence to date, which could have benefits in your clinical condition. At the same time, you will contribute to the advancement of scientific knowledge regarding this disease, which could bring future benefits to you and other patients. You will not receive any financial compensation for participating in this study.

CONFIDENTIALITY

The principal investigator of the study is responsible for the handling of personal data in accordance with the provisions of the Organic Law on Protection of Personal Data 3/2018, of December 5. It shall be assigned a numerical code according to a randomization scheme generated by a computer program; This code will be used to identify your data, without stating any other identifying data. Only the researcher and authorized persons related to the study will have access to this code. The information will be processed during the analysis of the results obtained and will appear in the final reports. Your data cannot be linked to you, even if the results of the study are published.

The personal data you have provided us for this research project will be treated with absolute confidentiality in accordance with the Data Protection Law. You can consult at any time the data you have provided us or ask us to rectify or cancel your data or simply not to use them for any specific purpose of this investigation.

ACCESS TO RESEARCH RESULTS

Although the patient will be able to know his own research results, it will not be possible to communicate any personal results obtained from other patients. However, it may ask the researcher for the overall results of the research carried out.

REVOCATION OF CONSENT

The participant has the right to revoke his/her consent and withdraw from the study at any time and without explanation. The cessation of your participation in the study will not affect your relationship with your traumatologist or physiotherapist or your future health care. Likewise, the participant has the right to request the Principal Investigator, Xabat Casado Zumeta, at any time, and without specifying the reason, the destruction of their data.

CONTACT DETAILS:

If you have any questions about your participation in this project or your rights as a patient, please contact:

Dn: Xabat Casado Zumeta. Phone: 613044885. P/ Heriz 10 bajo. 20008 Donostia.

INFORMED CONSENT

STUDY TITLE: Prediction of response to manual physiotherapy using somatosensory profiles in patients with cervicobrachialgia.

PRINCIPAL INVESTIGATOR: Xabat Casado Zumeta

CENTRE: University of Deusto / University of Deusto.

I, _____

(Name and surname of the patient in CAPITAL LETTERS)

I declare that,

- ✓ I have read and understood the fact sheet about this study.
- ✓ I have spoken with Xabat Casado Zumeta with whom I have clarified the possible doubts.
- ✓ I have asked all the questions I have asked about the study.
- ✓ I understand the purpose for which my personal data will be used.
- ✓ I understand that my participation is voluntary.
- ✓ I understand that I can withdraw from the study, whenever I want, without giving explanations and without affecting my medical care.
- ✓ I understand that the personal and family information I provide will be kept confidential and will not be shown to anyone without my consent.
- ✓ I understand that my participation in the study involves authorizing sensory evaluation of pain thresholds and clinical examination.

I CONSENT TO PARTICIPATION IN THIS STUDY:

☐ **YES** ☐ **NO**

To put all this on record, I sign below:

Date..... Signature.....

And I freely agree to participate in the study.

I, Xabat Casado Zumeta, declare to have explained the characteristics of the study and safety that will be applied to the associated clinical data.

Signature of the investigator responsible for patient information

Name and surname.....

Date:.....

SECTION FOR THE REVOCATION OF CONSENT

I, ...

Signature and Date of Revocation: