EFFECTIVENESS OF THE PERCUTANEOUS APPLICATION MUSCULAR ELECTROLYSIS SCAR TISSUE.

NTC ID not yet assigned

Unique protocol id: PI 2023 081418 - TD

20 NOVEMBER 2024

Printed IEC-A1

PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FOR RESEARCH PROJECTS IN PEOPLE WITH FULL CAPACITY

Qualification: "Effectiveness of the application of percutaneous electrolysis in muscular scar tissue"

IP: Fausto Jose Barbero Iglesias.

Introduction

You have been invited to participate in a research study. Please take your time to read the following information and ask questions. Ask the researcher for this study if there is anything that is not clear to you or if you would like more information.

This study investigates the effectiveness of percutaneous electrolysis in the treatment of muscle tears located in the calf. This technique is part of invasive physiotherapy and consists of the application of a galvanic current (low intensity direct current) through an acupuncture needle in an ultrasound-guided manner at the site of the injury, with the aim of reactivating the local inflammatory process and repairing the affected soft tissue.

Current scientific evidence tells us that this technique is effective in treating patients with various musculoskeletal disorders. Despite this, the application of this technique in muscle tears still does not have sufficiently conclusive results to extrapolate conclusions in this regard. That is why this study focuses on finding out how effective percutaneous electrolysis is in this type of injury.

Objective of the study

The aim of the study is to analyse the effectiveness of percutaneous electrolysis on muscular scar tissue, more specifically on the gastrocnemius muscles. The variables chosen to collect information on this effectiveness are the level of myofascial pain, the level of kinesiophobia (fear of movement), muscle fatigue and the joint range of the ankle with the knee extended.

This project has been approved by the Committee on Ethics for Drug Research of the Salamanca Health Area and follows the ethical recommendations of the Declaration of Helsinki.

Procedures

The study will be structured in such a way that two assessments will be carried out, one at the beginning of the study (day 1), before any intervention, and another two weeks after the 3rd intervention (day 28). The interventions will take place on day 1, day 7 and day 14. The study participants will be divided into three groups in a randomized manner and with concealed allocation. In all three groups, manual therapy of the triceps surae, mobilization of the subtalar joint and thermotherapy through diathermy will be performed. In addition to this, each group will receive an intervention consisting of the introduction of an acupuncture needle into the muscular scar tissue for 90 seconds. Two of these groups will receive a low intensity direct current (galvanic) through the needle (electrolysis).

percutaneous), while the third group will keep the needle without current (for later comparison). This is why you can be randomly included in any of these three groups.

As for the assessments, pain measurements will be taken using a VAS scale, data on the level of kinesiophobia will be collected using a questionnaire, a physical test will be performed to assess muscle fatigue and the joint range of the ankle with hip extension will be assessed by taking a photograph in which the lower limb will appear exclusively for the purpose of obtaining the degree of flexion of the ankle in relation to the leg using software, which will be deleted once the study is completed.

Do not hesitate to ask the researcher of this study if during the research you have not understood or if something has not been sufficiently clear to you.

Principle of nonmaleficence: Risks and inconveniences

Participation in this study does not cause any discomfort and does not entail any health risks. Percutaneous electrolysis is an invasive technique that consists of introducing a needle into the affected tissue to provide a galvanic current with certain parameters through the EPI device and produce the therapeutic response. The patient may notice a tingling sensation when the electric current passes through. The side effects that may occur are:

- Discomfort in the treated area that resolves within a few hours.
- Redness in the area that resolves within a few hours.
- Vasovagal syncope. It is commonly known as dizziness that can occur in some situations in which the patient is not comfortable, such as blood draws and other procedures with needles. The patient usually notices a sensation of heat, flushing, distress in some situations, and fainting.

Thermotherapy through diathermy is a non-invasive technique that consists of the application of a high-frequency current that induces hyperthermia (increase in temperature) in the tissues, for therapeutic purposes. The patient may notice a sensation of heat when the electric current passes through. The side effects that may occur are:

- Redness in the area that resolves within a few hours.

If you notice any of these symptoms, do not hesitate to tell your doctor. These symptoms are rare and if they do appear, they resolve within 24 to 48 hours. In the case of vasovagal syncope, they resolve within a few minutes.

During the recording of variables, an image will be taken once the patient is placed in the gastrocnemius stretching position. A digital camera (Canon EOS 2000D 24.1 MP) will be placed on the floor at a distance of 2 meters perpendicular to the plane of movement of the right leg to record the angle of dorsiflexion of the standing ankle. The angle of the ankle joint in stretching was analyzed by reflective markers placed on the knee (head of the fibula), the ankle (external malleolus) and the fifth metatarsal (head) using free software (RULER- Ergonauts Software. Polytechnic University of Valencia).

Transfer of data or samples

If your data is transferred to other research groups, this will always be done in accordance with current legislation, with your data encoded, and exclusively to carry out studies related to the objectives of this work, and with prior authorization from the Ethics Committee for Drug Research of the Salamanca Health Area. If the objectives of the research work proposed by other research groups are different from those of this project, you will be asked for a new consent.

☐ Yes, I agree that my data may be transferred to other research groups with the same objectives.

☐ I do not consent to the transfer of my data

Principle of autonomy and benefits of participation: Voluntary participation and withdrawal

You are free to decide whether or not you wish to take part in this study; participation is entirely voluntary. If you decide to participate, you still have the option to withdraw at any time without having to give any explanation, and without any penalty or negative consequences for you. If you decide to participate, you must commit to doing as best as possible what the research team tells you to do.

Right to information

Even if you do not directly benefit from your participation in this study, you will be collaborating in the development of scientific knowledge in physiotherapy and, specifically, in the technique of percutaneous electrolysis and in the approach to musculoskeletal disorders.

☐ Yes, I wish to obtain the research results that are relevant to me. I do not wish to
☐ receive information.

The information will be sent to you by email to the address you leave here:

_____.

Confidentiality and security measures

All information used during this study will be treated strictly confidentially in accordance with the privacy policy (see attached sheet).

An effective anonymisation system has been established which does not allow for subsequent identification of participants. Under no circumstances will the consent forms, where participants are identified, be combined with the questionnaires or other information used in the study. In the use of the results of the study for teaching, research and/or publication purposes, due anonymisation of personal data will always be respected, so that the research participants will not be identified or identifiable.

If the results of the study are likely to be published in scientific journals, personal data of the participants in this research will not be provided at any time.

It is important that you do not comment on the characteristics of the procedures or the objectives of this study until all the research has been completed.

Contact details of the research team:

Name: Fausto José Barbero Iglesias
Phone: 663-003-616

Name: Carlos Vicente Vega
Phone: 609-645-964

Name: Sergio Varela Rodriguez
Phone: 650-300-373

PRIVACY POLICY

Who processes your data?
The person responsible for processing your data
is: University of Salamanca
CIF Q3718001E
C/ Patio de las Escuelas Menores, No. 1
CP 37008, Salamanca

How can you contact our data protection officer?
The data protection officer is the person in charge of supervising that we comply with data protection regulations and helping you. If you have any questions or queries about how we process data, you can contact the data protection officer at: dpd@usal.es

What do we process your data for? Why and on what legal basis do we process your data?
We will process your data in order to manage your participation in the Research Project. Your data will be processed pursuant to:
Your consent (Article 6.1.a) GDPR), to participate in the Project, and the publication of the results, where applicable, in relation to the biographical references whose publication may be necessary in the Project.

Compliance with a mission carried out in the public interest or in the exercise of public powers conferred on the data controller (art. 6.1.e) GDPR) in accordance with the powers attributed to the University by virtue of articles 1 and 39 and following of Organic Law 6/2001, of December 21, on Universities.

Who do we share your data with?
▪ Data will only be communicated without the need to grant consent at the request of authorities.

In these cases, before making the data available to third parties, the University ensures that these authorities request and access the data in accordance with the Laws.

How long will we retain the data?
▪ The data will be used throughout the investigation until, where appropriate, a report is issued or the results of the investigation are published.
▪ The information will be kept duly blocked for the additional periods necessary for the prescription of possible legal responsibilities.
▪ Information with historical value will be kept indefinitely subject to prior approval by the Expungement Commission pursuant to the provisions of Law 16/1985, of June 25, on the Spanish Historical Heritage and the specific regulations applicable where applicable.

How do we protect information?
As a public administration, we apply the technical and organisational measures dictated by the National Security Scheme. This includes a series of recommendations to try to guarantee the security of information systems and thus avoid theft, alteration or unauthorised access to data. In the case of subcontracting services, we will require and ensure that the data processor applies measures similar to those of the National Security Scheme.

What rights do you have?
In order to maintain control over your data at all times, you have the right to access your personal information, as well as to request the rectification of inaccurate data or, where appropriate, request its cancellation or deletion. In certain circumstances, and for reasons related to your particular situation, you may object to the processing of your data. Likewise, you may exercise the right to limit the processing of your personal information, requesting that we retain it and also request the portability of your data.
The exercise of rights is personal and therefore we need to identify you unequivocally. You can exercise your rights in two ways:
▪ By sending an email message.

To do so, please use this address: dpd@usal.es . We will only process requests made from email accounts provided by the University of Salamanca or those that are included in our databases after identifying the owner.
▪ By submitting a written request to our Registry or by post to: General Secretariat

University of Salamanca.
CIF Q3718001E
C/ Patio de las Escuelas Menores, No. 1
CP 37008, Salamanca
You must provide the following supporting documentation:
▪ Proof of the identity of the interested party by means of any valid document, such as ID or passport.

▪ Name and surname of the interested party or, where applicable, of the person representing him/her, as well as the document proving such representation.
▪ Petition in which the request is specified.
▪ Address for notifications, date and signature of the applicant.
▪ Documents supporting the request you make, if applicable.
▪ In the case of rectification or cancellation, indication of the data to be rectified or cancelled and the reason justifying it.

Who guarantees your rights? Who can you complain to?
If you wish to file a complaint or obtain additional information regarding the regulation of personal data processing in Spain, the competent authority is the Spanish Data Protection Agency (Jorge Juan, 6 28001-Madrid).

INFORMED CONSENT FOR PERSONS WITH FULL CAPACITY

Qualification: Effectiveness of the application of percutaneous electrolysis in muscular scar tissue.

I *(Name, Surname and ID)*_____

I have been able to ask questions about the study.

I have received enough information about the study.

I have read the information sheet that has been given to me.

I am informed of how my data will be treated.

I have spoken with the Researcher_____

I understand that my participation is voluntary.

I understand that I may withdraw from the study:

1st Whenever you want.

2nd Without having to give explanations.

3º Without any negative repercussions.

I voluntarily agree to participate in the Project and authorize the use of all information obtained. I understand that I will receive a signed copy of this informed consent.

_____ _____

Signature of the participant Date

_____ _____

Name and signature of the researcher Date

REVOCATION OF CONSENT

I revoke the consent given on "_____ to participate in the project entitled "_____" and, for the record, I sign this revocation.

In , at _____ of _____ of 20___.

Signature of the participant Date

Name and signature of the researcher Date