INFORMED CONSENT C.I. PI24/578

Effectiveness of ultrasound-guided percutaneous electrical stimulation of the inferior gluteal and superior gluteal nerves as a treatment for gluteus maximus and gluteus medius muscle dysfunction after an episode of low back pain: a randomized clinical trial.

PARTICIPANT INFORMATION DOCUMENT

Title of the research:
Effectiveness of percutaneous electrical stimulation ultrasound-guided of the inferior gluteal and superior gluteal nerves as a treatment for gluteus maximus and gluteus medius muscle dysfunction after an episode of low back pain: a randomized clinical trial.

Promoter: Marc Badia Rosells

Principal Investigator Marc Badia Rosells **Tfno:** 605635801 **mail:** marcbadia.fisio@gmail.com

Center: University of Zaragoza - Physiotherapy Clinic Fiostec Funcional

Introduction:
We are writing to you to request your participation in a research project that we are carrying out from the University of Zaragoza in collaboration with the physiotherapy clinic Fiostec Funcional in Sabadell. Your participation is voluntary, but it is important to obtain the knowledge we need. This project has been approved by the Ethics Committee, but before making a decision it is necessary that:

- Read this entire document
- Understand the information contained in the document
- Ask as many questions as you consider necessary
- Make a thoughtful decision
- Sign the informed consent form, if you finally wish to participate.

If you choose to participate, you will be given a copy of this sheet and the signed consent form. Please keep it in case you need it in the future.

2. Why are you being asked to participate?
Your collaboration is requested because you have suffered an episode of low back pain and you may have an alteration in the function of the gluteal musculature. A clinical trial is going to be carried out to evaluate whether a treatment to recover muscle function is more effective than the treatment currently being applied.

A total of 24 patients with gluteal muscle dysfunction will participate in the study.

3. What is the object of this study?

The study will make it possible to evaluate whether modifying part of the current treatment for gluteal muscle dysfunction after an episode of low back pain will achieve more and better effects than using the current treatment.

What do I have to do if I decide to participate?

To assess their participation, their clinical history will be evaluated and periodic evaluations will be carried out in person at the beginning, prior to the intervention, at the end of the second and fourth week after the end of the intervention (approximately 20 minutes for each evaluation).

The total duration of the study will be 4 weeks, from the time the first evaluation is performed and a group is randomly assigned within the study. There will be two groups: the group that will receive stimulation at a frequency currently used at 10Hz and the group that will receive stimulation at a higher frequency, 20-100Hz. The decision of the group assignment will be made randomly through a computer program by a person outside the study and the medical and health professionals will not know which group they belong to except for the physiotherapist who directs the intervention in the groups.

The procedure is performed in the upper region of the buttock, introducing an acupuncture needle guided by imaging ultrasound at all times, and applying electrical stimulation of the upper and lower gluteal nerve. The electrical stimulation is painless and completely bearable, the puncture may cause a brief pricking sensation or painmomentary . The differences between the stimulation groups are only with respect to the frequency, (cycles per second), so participants in the stimulation groups only will receive the same stimulation at more or less speed.

In relation to the intervention, the same technique will be applied to both groups in the same location.

All evaluation and intervention sessions will be free of charge for all participants. The only expense incurred will be the one derived from travel to the physiotherapy clinic Fiostec Functional where all face-to-face evaluations will be carried out.

5. What are the risks or inconveniences involved?

The performance of the intervention for the functional improvement of the gluteal musculature in patients with gluteal muscle inhibition is not expected to have any type of adverse effect. The possible adverse effects that may derive from the intervention are those typical of any intervention with puncture in the field of physiotherapy, which can be summarized as small hematomas and local pain of short duration due to the mechanical effect of the puncture. These effects will be monitored by the investigators and will be recorded within the study.

The performance of the procedure may cause discomfort or a pain slight prick momentarily due to the act of puncture, which is performed with a needle.very fine acupuncture

6. Will I receive any benefit for my participation?

Since this is a research study aimed at generating knowledge, it is unlikely that you will not receive any benefit for your participation, although you will contribute to scientific advancement and social benefit. You will not receive any financial compensation for your participation.

7. How will my personal data be treated?

Basic information on data protection.

Responsible for the treatment: Marc Badia Rosells

Purpose: Your personal data will be processed exclusively for the research work referred to in this document. **Legitimation**: The processing of the data in this study is legitimized by your consent to participate. **Recipients**: No data will be transferred to third parties unless legally required.

Rights: You may exercise your rights of access, rectification, deletion and portability of your data, limitation and opposition to its processing, in accordance with the provisions of the General Data Protection Regulation (RGPD 2016/679) to the manager of the University of Zaragoza (gerente@unizar.es) or to the principal investigator of the project, whose contact details appear in the heading of this information.

If your request is not answered, please know that you can go to the Data Protection of the University of Zaragoza Delegate (dpd@unizar.es- Tfno. 876 55 36 13) or, in complaint, to the Spanish Data Protection Agency (www.aepd.es).

Additional detailed information on the protection of personal data of the University of Zaragoza can be found on the following page (http://protecciondatos.unizar.es/) and on this specific processing in the Inventory of Processing Activities of the University of Zaragoza (https://protecciondatos.unizar.es/registro-actividades-de-tratamiento).

The processing of your personal data will be carried out using techniques to maintain your anonymity through the use of random codes, so that your personal identity is completely hidden during the research process.

Based on the results of the research work, scientific communications may be prepared to be presented at congresses or scientific journals, but they will always be done with grouped data and nothing that could identify you will ever be disclosed.

Data collection will be carried out through the computer application HEFORA, designed for the management of clinical and research data and which, for these purposes, acts as Data Processor. These data will only be accessible by the research team and their publication will always be done in aggregate form after statistical processing, after application of the corresponding techniques of anonymization of personal data, these being irreversible. You can consult and access to its privacy policy at https://es.hefora.com/

8. Who is financing the study?

This project has no external funding.

9. Will I be informed of the results of the study?

You have the right to know the results of this study, both the general results and those derived from your specific data. You also have the right not to know the results of this study if you wish to do so. For this reason in the informed consent document we will ask you which option you prefer. If you do wish to know the results, the investigator will send you the results.

10. Can I change my mind?

Your participation is completely voluntary, you may decide not to participate or to withdraw from the study at any time without having to give explanations and without any repercussions on your health care. It is sufficient for you to express your intention to the principal investigator of the study.

If you decide to withdraw from the study, you may request the destruction of your data at any time without explanation.

11. What happens if I have questions during my participation?

The name and contact telephone number of the investigator responsible for the study are listed on the first page of this document. If you have any questions about your participation, please contact him/her.

Thank you very much for your attention, if you finally wish to participate we kindly ask you to sign the attached consent form.

INFORMED CONSENT FORM

PROJECT TITLE: Effectiveness of percutaneous electrical stimulation ultrasound-guided of the inferior gluteal and superior gluteal nerves as a treatment for gluteus maximus and gluteus medius muscle dysfunction after an episode of low back pain: a randomized clinical trial.

Mr./Mrs. .....
(participant's name and surname), I declare that:

I have read the information sheet provided to me.
I have been able to ask questions about the study and have received sufficient information about the study.
I spoke with: Marc Badia Rosells, member of the research team.
I understand that my participation is voluntary.
I understand that I can withdraw from the study:
1) Whenever you want
2) Without having to explain
3) Without affecting my medical care.

I freely give my consent to participate in this study and consent to the access and use of my data as stipulated in the information sheet provided to me.
I wish to be informed about the results of the study:
YES / NO

I agree that the data may pseudonymized derived from this study be used in the future in projects of the "Invasive Physiotherapyresearch line" , for which Dr. Pablo Herrero Gallego is responsible, provided that they have obtained the favorable opinion of a Research Ethics Committee and have requested the appropriate permissions:
YES / NO

I consent to have my clinical data reviewed by personnel outside the center for the purposes of the study, and I am aware that this consent is revocable.
I have received a signed copy of this Informed Consent.
Participant's signature:

Date: .....

I have explained the nature and purpose of the study to the aforementioned patient.
Investigator's signature:

Date: .....