# Efficacy of Dry Needling in Plantar Fasciitis

NCT number: 02467465

Madrid, 23th april 2014.

## INFORMED CONSENT:

**INFORMED CONSENT TO PARTICIPATE IN AN INVESTIGATION STUDY**

Protocol title: Efficacy of needling in plantar fasciitis.

Researcher: D. Miguel Suárez Varela.

Venue where the study will be carried out: University Podiatry Clinic, Faculty of Medicine, Complutense University of Madrid

Patient's name: _____ DNI: _____

You are being invited to participate in this research study. Before deciding whether or not to participate, you should know and understand each of the following sections. This process is known as informed consent. Feel free to ask about any aspect that helps you clarify your doubts.

Once you have understood the study and if you wish to participate, then you will be asked to sign this consent form, which will be given a signed and dated copy.

JUSTIFICATION OF THE STUDY

Plantar fasciitis, or as it is commonly known, plantar fasciitis is a major health problem with increasing social and economic consequences. It is defined as pain in the sole of the foot, especially in the heel in the first steps of the morning and when walking after long periods of rest. The discomfort is due to the alteration of the plantar fascia, a structure that is located on the sole of the foot that goes from the heel to the toes. Patients with plantar fasciitis are 15% of all foot visits to the doctor. The intense pain located in the heel and the discomfort it produces seriously alter the day to day of the patient who suffers it. To this day, the causes that cause it are still being studied, which hinders the development of a treatment that helps us to solve it. This situation forces us to carry out this study in order to develop new treatment routes to improve the approach, understanding and treatment of plantar fasciitis itself.

OBJECTIVES OF THE STUDY

You are being invited to participate in a research study that aims to verify the efficacy of dry needling along with a physical therapy treatment consisting of manual therapy and home exercises, aimed at normalizing muscle tone and inhibiting myofascial trigger

points in the muscles of twins and soleus located in the back of the legs, in patients diagnosed with plantar fasciitis, compared to patients receiving the same physiotherapy treatment but without a dry puncture.

STUDY BENEFITS

In previous studies by other researchers, it has been observed that the application of dry puncture to lesions located in other regions of the body, such as the neck or back, has been effective for the treatment of myofascial trigger points and therefore for the resolution of clinical picture, reduction of pain and improvement of the quality of life of the patient.

This study aims to treat the myofascial trigger points of musculature intimately involved in the appearance of plantar fasciitis as well as its maintenance over time, solving the discomfort caused by fasciitis, such as pain in the early morning steps, pain after long periods of rest, the limitation of the mobility of the foot, the alterations and the compensations that it forces to carry out during the march and the negative consequences that it can have on the activities of daily life and work.

This study will allow other patients to benefit from the knowledge obtained and optimize the treatment of patients suffering from plantar fasciitis in the future, reducing recovery time, costs and effort.

STUDY PROCEDURES

If you agree to participate in the study, some questions will be asked about you, your habits, and your medical history. You will be included in one of the study groups and, depending on the group to which you belong, you will receive the dry puncture application plus the conventional physiotherapy treatment, or only the conventional physiotherapy treatment. Physiotherapy treatment for plantar fasciitis consists of a leg and foot stretch table, manual therapy work on the leg and foot, and mobilizations of the ankle and foot joints. Dry puncture consists of using the mechanical stimulus caused by a needle, such as acupuncture, as a physical agent for the treatment of myofascial trigger points. The adjective "seca" is used to highlight the fact that no chemical agent is introduced into your body.

PHASES OF THE STUDY:

Initial visit (day 1):

On the first day, the patient will undergo a complete clinical measurement: weight, height, BMI, dorsal flexion measurement with knee flexion and extension by goniometry, bilateral plantar fascia ultrasound, assessment of quality of life using the SF-36 questionnaire. and the measurement of pain through the EVA and by algometer at the origin of the plantar fascia in the heel. After registering the date and the variables mentioned above, the patient will be assigned to the group that will integrate throughout the research and based on this, the corresponding FP treatment will be carried out in the same session for 45 minutes.

Second visit (day 2) and third visit (day 3):

Application of the treatment depending on the group that integrates each patient.

Fourth visit (day 4 or month 1):

Application of the treatment depending on the group that integrates each patient. Reevaluation: new measurement of the variables collected at the beginning of the study. Maintenance of the intervention, only with home exercises.

Fifth visit (month 3):

The intervention ends: measurement of the variables collected at the beginning of the study. Upon completion of the study, all patients who require it will be offered the same treatment options.

STUDY RISKS:

In previous studies, no case of adverse or secondary effect has been described. There may also be unpredictable risks that are beyond our knowledge. In the event that you develop any adverse side effect or require other care, it will be provided to you under the terms that have always been offered to you.

CLARIFICATIONS:

Your decision to participate in the study is completely voluntary.

There will be no unfavorable consequences for you if you do not accept the invitation.

If you decide to participate in the study, you can withdraw at the time you wish, even when the responsible researcher does not request it, informing the reasons for your decision, which will be respected in its entirety.

You will not have to make any expenses during the study, at more than the cost of a physiotherapy session at the University Clinic of Podiatry, Faculty of Medicine, Complutense University of Madrid.

You will not receive payment for your participation.

In the course of the study, you may request updated information about it from the responsible researcher.

The information obtained in this study, used to identify each patient, will be kept with strict confidentiality by the researcher in accordance with the Organic Law on Data Protection (LOPD 15/1999, of December 13).

If you believe that there are no doubts or questions about your participation, you can, if you wish, sign the Informed Consent Letter attached to this document.

The use of the data provided by these studies is exclusively for the investigation of the therapeutic efficacy of dry needling in patients diagnosed with plantar fasciitis. The results will be communicated in the usual means of scientific dissemination, including oral presentations or in poster format at conferences, workshops or other meetings of scientific interest; technical publications and other means of professional dissemination, always safeguarding the privacy of the patient and her known pathological processes.

The data of the patients collected in the present study will be managed by the researcher D. Miguel Suárez Varela. These data are subject to the regulatory legislation by Organic Law on Data Protection (LOPD) 15/1999, of December 13 and to law 41/2002, of November 14, basic regulation of patient autonomy and rights and obligations in matter of clinical information and documentation. The data will be included in a Research File whose responsible will be the center and that the patient may exercise their rights of access, rectification, cancellation or opposition by contacting the center or the researcher.

ECONOMIC MEMORY:

Acupuncture needles (€ 50), sterile gloves (€ 30), dressings (€ 40), chlorethyl (€ 10) and 96o alcohol (€ 6).

All these figures are estimated and the expenses that these materials generate will be borne by the researcher.

INFORMED CONSENT LETTER

I, _____ have read and understand the above information and my questions have been satisfactorily answered. I have been informed and understand that the data obtained in the study may be published or disseminated for scientific purposes. I agree to participate in this research study. I will receive a signed and dated copy of this consent form.

Participant's Signature Date

This part must be completed by the Investigator (or her representative):

I have explained to Mr (a). _____ the nature and purposes of the investigation; I have explained to you about the risks and benefits of participating. I have answered the questions as much as possible and asked if you have any questions. I accept that I have read and know the corresponding regulations for conducting research with human beings and I adhere to it.

Once the question and answer session was over, this document was signed.

Investigator's Signature Date

CONSENT REVOCATION LETTER

Protocol title: Efficacy of dry needling in plantar fasciitis.

Main researcher: D. Miguel Suárez Varela

Venue where the study will be carried out: University Podiatry Clinic, Faculty of Medicine, Complutense University of Madrid

Participant's name: _____

Through this channel I wish to inform my decision to withdraw from this research protocol for the following reasons:

Participant's Signature Date