Efficacy of Dry Needling in Plantar Fasciitis

NCT number: 02467465

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PROTOCOL:

RANDOMIZATION OF THE SAMPLE

Prior to the assignment of the patient to a study group, the following activities will be carried out:

- Assessment of the selection criteria.
- Information to the patient about the objectives and implications of the study.

  Delivery of an information sheet and Informed Consent. In addition, they will be informed of the confidentiality of their data in accordance with the Organic Law 15/99 of December 13 on the Protection of Personal Data (LOPD).

- The assignment of patients to the intervention groups will be carried out using simple randomization methods, with random number tables. In order of arrival to the study, each subject will be assigned a number from this table (from top to bottom in the columns, starting with the column on the left and to the right). In case this number is even, the patient will be assigned to the experimental group; if it is odd, it will be assigned to the control group.
- The patient will not know until the end of the study the group to which he / she belonged. The history number will be coded by the researcher who will recruit the patients based on a table of alphanumeric equivalences. The sequence of randomization will only be known by the researcher and will be dissociated from the patient's Clinical History to ensure that only the researcher can relate this data to the patient.
- The only person who will know which group is assigned to each patient will be the researcher; which will be in charge of carrying out all the research, except for the section of the ultrasound, whose work will correspond to a doctor with experience in the use of said diagnostic technique.

DESCRIPTION OF THE THERAPEUTIC PERFORMANCE PROTOCOL

Physiotherapy treatment:

The control group will receive a standard treatment for the rehabilitation of plantar fasciosis based on the evidence found in the literature search. Said physiotherapy treatment will consist of passive ankle and hindfoot mobilization techniques, massage therapy and stretching in the gastrosoleus complex, and home exercises consisting of performing autopassive stretches in unloading this musculature daily in 3 repetitions of 30 seconds with intervals of others. so many seconds of rest between one repetition and another.

The stretching maneuvers during each session of the intervention will be performed with the patient lying prone on the stretcher, keeping the knee of the limb treated, flexed 90o when the muscles to stretch is the soleus muscle and with the knee in full extension when the maneuver will be applied to the gastrocnemius. Through this positioning of the patient, the force performed by the therapist to achieve the desired effect should be applied to the plantar aspect of the forefoot, at the level of the metatarsal heads. In this way, the ankle will be brought to dorsiflexion and the movement will be centered on the posterior musculature of the leg.

This intervention will be made common to both control and experimental groups. Both groups will receive their respective treatments established in the protocol in 4 sessions of physiotherapy, once a week, until completing 1 month of treatment. After the month of treatment, it will be interrupted and only the intervention of the domiciliary exercises will be maintained until the sixth month, when the study will end. Once the research phase of the study is completed, the therapy will be offered to all patients who request it.

Physiotherapy and dry needling treatment:

As described, the experimental group will receive the same treatment as the control, adding the intervention with dry puncture applied at the level of the twins and the soleus of the leg corresponding to the affected member according to the protocol of the Hong technique. Regarding the characteristics of the needle, say that its length will depend on the location of the myofascial trigger point in question.

The necessary material will be:

- Needles: filiform needles that initially will have a length of 4 cm (although it can vary)

and a diameter of 25 mm. The needles will be for single use only. Sterile Ener-Qi acupuncture needles were used. CE 0197. Novosan, SA. Medical & HealthProducts

(www.novosan.es), manufactured by Suzhou Acupuncture Medical Applicance Co. Ltd No. A. Chuangxin Industrial Zone. Weitang Town Xiang Cheng District Suzhou City.

- Sterile gauze.
- Alcohol 96o or chlorhexidine.
- Gaseous hyperbaric cryotherapy with CO2.
- Marker marker demographic.
- Bats.
- Latex gloves.

Based on the protocol designed by Cotchett et al for a clinical trial, the number of insertions per muscle will depend on the number of trigger points as well as the tolerance of patients to dry needling, tissue responses and grade of pain after removal of the needle. This group of authors states that the most common is that the number of punctures is from 1 to 5. Finally, a Hong CZ study allows us to determine the intervention to be performed:

1) Assessment and data collection.
2) Have all the material prepared.
3) Locate the taut band in the patient.
4) Find the hypersensitive nodule within said taut band: myofascial trigger point.

5) Marker the location of the myofascial trigger point.

6) Disinfect the puncture site: with 96o alcohol or chlorhexidine.
7) Apply the parameters described in Hong's dry puncture technique:

- Insertion of the needle to the level of the underlying bone, when the puncture is in plane. If it is done with a clip, the insertion would be until you feel pressure on our fingers located on the opposite side.

- Back slightly with the needle until reaching the myofascial trigger point to be treated.

- Handling of the needle by rapid entry and exit, changing needle or skin orientation.

- If there is no response from the patient or if the patient does not support the pain produced in the maneuver: remove the needle (maximum 3 minutes).

8) Posterior hemostasis by direct compression.
9) Application of Cold Spray & Stretch (stretch of punctured muscle).
10) Self-stretching exercises without resistance: up to 2 days after the puncture.

Workplan:

- First appointment (day 1):

During the first appointment, the patient will undergo a complete clinical measurement, which will include: weight, height, BMI, measurement of the dorsiflexion range of the ankle, with the knee flexed and in extension, using goniometry. Likewise, the ultrasound measurement of the plantar fascia of the affected foot will be made, comparing it in turn with that obtained in the healthy contralateral limb. In addition, a pain assessment will be done through the VAS.

After the registration of the date and the aforementioned variables, the patient will be assigned to the group that will be part of the investigation and based on this, in the same session, the treatment of plantar fasciosis will be carried out for 45 minutes.

- Second appointment (day 2) and third appointment (day 3):
Application of the treatment to each patient, depending on the assigned study group.

- Fourth appointment (day 4 or month 1):

Application of the treatment according to the group that integrates each patient. Re-evaluation: new measurement of the variables collected at the beginning of the study. Maintenance of the intervention, only with domiciliary exercises.

- Fifth appointment (month 3):

Measurement of the variables collected at the beginning of the study.

- Sixth appointment (month 6):

After the intervention: measurement of the variables collected at the beginning of the study.