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Minimally invasive, ultrasound-guided therapy in patients with plantar fasciitis / fasciosis: a randomised study.

Submission date
20/12/2023

Recruitment status
No longer recruiting

Registration date
23/01/2024

Overall study status
Completed

Last Edited
22/01/2024

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Corticosteroid infiltration is commonly used for the treatment of plantar fasciitis. In recent years, ultrasound-guided multipunction treatment in the fascia has been described in the literature. This study aims to compare the effectiveness of the above techniques in the treatment of plantar fasciitis.

Who can participate?
Patients aged 18 years old and over diagnosed with plantar fasciitis

What does the study involve?
Patients in this study will be randomly assigned to receive either ultrasound-guided multipunction or ultrasound-guided corticosteroid infiltration for the treatment of plantar fasciitis. The intervention involves a single treatment session performed by an experienced podiatrist specializing in ultrasound-guided foot and ankle treatment. Clinical assessments, including a Visual Analog Scale for pain and The Foot Function Index for function evaluation, will be conducted before treatment and at 30, 60, and 120 days. Ultrasound will be used to measure the thickness of the plantar fascia at these intervals.

What are the possible benefits and risks of participating?
The possible benefits for the participants are to obtain healing of their plantar fasciopathy and improve their function and pain.

The possible disadvantages are the uncertainty about a new treatment whether it will have the ability to improve its pain and function and in what time frames this will happen.

Where is the study run from?
University of Seville

When is the study starting and how long is it expected to run for?
January 2022 to May 2024

Who is funding the study?
University of Seville

Who is the main contact?
Rubén Montes Salas, rubmonsal@alum.us.es

Contact information

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Scientific

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Additional identifiers

Protocol serial number
MP

Study information

Scientific Title
Investigating the efficacy of ultrasound-guided multipunction (MP) treatment versus ultrasound-guided corticosteroid infiltration (CI) in patients with plantar fasciitis / fasciosis.

Study objectives

Corticosteroid infiltration is commonly used for the treatment of plantar fasciitis. In recent years, ultrasound-guided multipuncture treatment in the fascia has been described in the literature. This study aimed to compare the effectiveness of the above techniques in the treatment of plantar fasciitis.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/02/2022, CEIC Valme University Hospital (CEIC Hospital Universitario de Valme) (Ctra. de Cádiz, km. 548,9, Seville, 41014, Spain; +34955015090; vicente.viruel.exts@juntadeandalucia.es), ref: 2093-N-21

Study design
Randomized controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Plantar fasciitis / fasciosis

Interventions
Patients will be randomly selected to be treated with either ultrasound-guided multipunction or ultrasound-guided corticosteroid infiltration. The assignment to one group or another was carried out according to their telephone number, being from one group if the number was even and to another if the number was odd.

The intervention is to perform one single treatment session of ultrasound-guide multipunction in patients diagnosed with plantar fasciitis. Control treatment is performing one ultrasound-guided corticosteroid infiltration. The procedures will be performed by a podiatrist who specialises in ultrasound-guided treatment of the foot and ankle with more than 10 years of experience.

Ultrasound-guide multipunction technique: before performing the technique, all subjects had the posterior tibial nerve anesthetized using truncal anesthesia with 2% mepivacaine as follows: after covering the ultrasound probe with the 3M TEGARDERM transparent sterile dressing, aqueous chlorhexidine 2% was sprayed to maintain skin asepsis. Aqueous chlorhexidine is also sprayed on the patient's foot and ankle. With the patient in a prone position, after waiting for the antiseptic to take effect, the posterior tibial nerve is located with the ultrasound in the area proximal to the internal malleolus, introducing the syringe loaded with local anesthetic and a 27G needle through the skin until reaching the perineurium under ultrasound vision in the long ultrasound axis, subsequently introducing 5 ml. of 2% mepivacaine.

Continuing with the patient in a prone position, in the case of the multipuncture technique, the depth of the puncture is measured with the ultrasound, and in an approach from the medial aspect of the foot, the 21G needle is introduced through the skin, under ultrasound visualization

of the entire needle, we make punctures on the plantar fascia multiple times until the entire area of most abnormality of the fascia is covered with several punctures.

Ultrasound-guided corticosteroid infiltration. technique: Before performing the technique, all subjects had the posterior tibial nerve anesthetized using truncal anesthesia with 2% mepivacaine as follows: after covering the ultrasound probe with the 3M TEGARDERM transparent sterile dressing, aqueous chlorhexidine 2% was sprayed to maintain skin asepsis. Aqueous chlorhexidine is also sprayed on the patient's foot and ankle. With the patient in a prone position, after waiting for the antiseptic to take effect, the posterior tibial nerve is located with the ultrasound in the area proximal to the internal malleolus, introducing the syringe loaded with local anesthetic and a 27G needle through the skin until reaching the perineurium under ultrasound vision in the long ultrasound axis, subsequently introducing 5 ml. of 2% mepivacaine.

Also with the patient in a prone position, the depth of the drug infiltration is measured with the ultrasound, and in a medial approach, 1 ml of a drug solution composed of 5.7 mg of betamethasone is infiltrated. , 3 mg of betamethasone (as sodium phosphate) and 2.7 mg of betamethasone (as 3 mg of betamethasone acetate) plus 1 ml of 2% mepivacaine, two-thirds of the volume being injected deep into the fascia and one-third of the volume superficial to it, under ultrasound visualization of the entire needle.

A clinical examination was performed and an ultrasound was taken before treatment and at 30, 60 and 120 days. Clinical assessments were made using a visual analog scale to record pain and The Foot Function Index to evaluate function. Ultrasound was used to determine the thickness of the plantar fascia.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Change in patient-reported pain measured using the Visual Analog Scale (VAS) to record pain at baseline and 30, 60 and 120 days following the end of treatment

Key secondary outcome(s))
1. Change in foot function measured using the Foot Function Index (FFI) at baseline and 30, 60 and 120 days following the end of treatment
2. Plantar fascia thickness measured using ultrasound at baseline and 30, 60 and 120 days following the end of treatment

Completion date
31/05/2024

Eligibility

Key inclusion criteria
1. Aged 18 years old and over
2. Symptoms compatible with plantar fasciitis
3. Thickening of the plantar fascia greater than 0.4 cm
4. Consenting to participate in the study

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
120 years

Sex
All

Key exclusion criteria
1. Systemic disease
2. Non-podological morpho-functional alterations that could have an impact on the ankle and foot and that could give rise to important clinical discrepancies in the lower limbs, dissymmetries or obvious clinical scoliosis
3. Having received any treatment (medical, orthopedic and /or invasive) in the foot in the last three months
4. Plantar fasciitis associated with another condition such as nerve entrapment
5. Difficulty in understanding the instructions to follow during treatment

Date of first enrolment
01/02/2024

Date of final enrolment
29/02/2024

Locations

Countries of recruitment
Spain

Study participating centre
Universidad de Sevilla. Facultad de Enfermería, Fisioterapia y Podología
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Sponsor information

Organisation
Universidad de Sevilla

ROR
https://ror.org/03yxnpp24

Funder(s)

Funder type
University/education

Funder Name
Universidad de Sevilla

Alternative Name(s)
University of Seville

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Spain

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication