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Shock waves versus corticosteroids infiltration for treatment of chronic plantar fasciitis

Submission date
18/09/2014

Recruitment status
No longer recruiting

Registration date
17/10/2014

Overall study status
Completed

Last Edited
24/07/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Plantar fasciitis is a painful condition of the foot. It happens when a band of tissue, called the plantar fascia, is damaged and becomes thickened and inflamed. Treatment involves a variety of techniques, including stretches and painkillers. In some cases, corticosteroid injections may be prescribed (corticosteroids infiltration). Corticosteroids are powerful anti-inflammatories and should only be used sparingly, due to side effects such as putting on weight. A recent alternative to extracorporeal shock wave therapy. This involves using a device to apply high-energy shock waves into the affected heal. It is thought that the treatment works by numbing the nerves causing the pain and stimulating the healing process. Here, we want to compare corticosteroids infiltration to shock wave therapy to see which is the best treatment for plantar fasciitis.

Who can participate?
Patients aged over 40 with plantar fasciitis, with foot pain lasting more than 6 weeks and a history of unsuccessful treatments for the condition.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 receive the shock wave therapy. Those in group 2 receive the corticosteroids infiltration. All participants are then followed up at 3 weeks, 6 weeks and 12 weeks after treatment, when their level of pain, foot function and general quality of life are assessed.

What are the possible benefits and risks of participating?
Both types of treatment are already well established as treatments for plantar fasciitis. There is no additional risks to participating in the study.

Where is the study run from?
The Department of orthopaedics and Traumatology, Federal University of São Paulo (Brazil)

When is the study starting and how long is it expected to run for?
April 2014 to April 2015

Who is funding the study?
Funding Authority for Studies and Projects, Ministry of Science and Technology (Brazil)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1873/07

Study information

Scientific Title
Shock waves versus corticosteroids infiltration for treatment of chronic plantar fasciitis: Randomised clinical trial

Study objectives
The hypothesis is that shock waves are more effective than corticosteroid infiltration for treatment of chronic plantar fasciitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee for Research - Federal University of São Paulo (Comitê de Ética em Pesquisa Universidade Federal de São Paulo) (CEP UNIFESP) - Escola Paulista de Medicina; ref. 0231/11

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic Plantar Fasciitis

Interventions
Patients are randomised to two groups:
1. Shockwave therapy
1.1. Patient lying down in supine position at the stretcher, without shoes, with ear plugs, with feet towards the shock waves device.
1.2. Mark the application place in the medial region towards the inferior calcaneal tuberosity.
1.3. Asepsis and antisepsis of foot and ankle.
1.4. Anesthetic block with 5ml of lidocaine hydrochloride at 2% of the tibial nerve in the medial retromalleolar region, 15 to 20 minutes before application.
1.5. Application of conductive gel in the heel plantar region.
1.6. Put the applying part (of the device) directly in the application zone in the heel plantar region.
1.7. Single application of 900 pulses, with energy about 0.13 mJ mm2 frequency of 4 pulses s with Evotron (Switch) device.
2. Corticosteroid Infiltration
2.1. Mark the application place in the medial region towards the inferior calcaneal tuberosity.
2.2. Asepsis and antisepsis of foot with Chlorhexidine gluconate at 2%.
2.3. Injection of 1 ml of betamethasone dipropionate (5 mg/ml) and of betamethasone disodium phosphate (2 mg/ml) and 1ml of lidocaine hydrochloride at 2% without vasoconstrictor at the maximum pain point.
Follow up with 3 weeks, 6 weeks and 12 weeks after both treatments, applying the scales VAS, AOFAS and SF36 by distinct teams from the ones that did the application.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pain evaluation in all cases will be carried out by an evaluator according to the visual and analogical scale for pain in the foot with plantar fasciitis after any intervention (Shock waves Therapy or corticosteroids infiltration). This scale was described by Revill et col. (1976); in it, the patient marks the intensity of his pain in a blank sheet of paper, with an X alongside a 10 cm line, measuring the distance from zero to X with a millimeter rule and the value written down in centimeters, with one decimal place. Zero is absence of pain and 10 cm is maximum pain.
2. The hindfoot function of the patient with plantar fasciitis, after treatment with Shock waves Therapy or corticosteroids, will be evaluated through the AOFAS questionnaire.
3. Quality of life of the patient with plantar fasciitis after treatment with Shock waves Therapy or corticosteroids will be evaluated through the SF-36 questionnaire.Use of a quality of life evaluation questionnaire is required to correlate specific aspects of an illness with the overall health condition of the person. SF-36 (The Medical Outcomes Study 36-item Short-Form Health Survey) questionnaire is a generic tool for evaluating quality of life, i. e., it may be used for any illness, age or treatment group.

Secondary outcome measures
1. Occurrence of inflammatory or infectious process in the region of local anesthesia or corticoid infiltration.
2. Necrosis of skin in the region of anesthetic block or corticoid infiltration.
3. Use of rescue medication (dipyrone).
4. Relation of B.M.I. with the post-intervention evolution.

Evaluation of Outcomes:
Use of analgesics post-application (rescue)
1. If pain gets worse soon after any of the established treatments, the patient will be allowed to use an analgesic (dipyrone) for a period of 5 days. Medication will be provided to the patient after intervention with instructions about how and in what situation it must be used.
2. After the 5-day period of analgesia, in case of persistent pain, the patient will be re-evaluated, and the need for change of medication will be checked.
3. After the second evaluation (in 6 weeks), if pain is worse than it was before the treatment, it will be proposed to the patient the change of treatment for the other method (infiltration of shock waves) or his exclusion from the work, if the patient so wants.
4. It will be excluded from the study the patient who receives another type of treatment, on his own, during the study.
5. Criteria for worsening:
VAS higher than initial evaluation. SF-36 and AOFAS lower than initial evaluation. Worsening referred by the patient.
6. Criteria for unchanged situation: VAS, SF-36 and AOFAS unchanged in relation to the initial evaluation.
7. Criteria for improvement: VAS lower than initial evaluation. SF-36 and AOFAS higher than initial evaluation.

Overall study start date
18/04/2014

Completion date
01/04/2015

Eligibility

Key inclusion criteria
1. Older than 40 years, for both sexes
2. Patient with unilateral chronic plantar fasciitis, diagnosed by clinical examination
3. Symptoms of heel pain in the region of plantar fascia insertion, for more than 6 weeks
4. History of unsuccessful previous conservative treatment, including one, or an association of, the following therapeutic methods: NSAID (non-steroidal anti-inflammatory drugs), rest, heat, ice, ultrasound, massage, orthoses, plaster immobilization, taping, change of footwear and use of night orthosis.
5. Physical examination with pain to palpation of the plantar fascia insertion in the unilateral calcaneus inferomedial region
6. Ultrasound examination of affected foot showing inflammatory process in the plantar fascia insertion region, in the calcaneus inferior part

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. History or documented evidence of autoimmune or peripheral vascular disease
2. History or documented evidence of type 1 or type 2 Diabetes mellitus (possibility of diabetic peripheral neuropathy)
3. History or documented evidence of peripheral neuropathy (Nerve Compression Syndrome, Tarsal Tunnel Syndrome)
4. History or documented evidence of systemic inflammatory disease (reumathoid arthritis, ankylosing spondylitis, Reiters Syndrome, etc.)
5. History or documented evidence of loss of feeling in foot or ankle
6. Pregnancy
7. Reflex sympathetic dystrophy
8. Congenital club foot
9. History or documented evidence of blood coagulation disorders (treatment with anticoagulant, except for aspirin)
10. Treatment with corticosteroid injection in less than 30 days
11. Previous surgical treatment for plantar fasciitis
12. Use of cardiac pacemaker
13. Allergy or known allergic sensitivity to lidocaine or corticosteroids
14. Active infectious process (superficial on the skin and cellular subcutaneous tissue or deep in the bone) in the region to be treated
15. Nonpalpable posterial tibial pulse or pedal pulse, or abnormal capillary refill
16. Tumoral (main or secondary tumors), traumatic (fracture) or infectious (osteomyelitis) lesions
17. Stress fracture
18. Radiographic examination of the affected foot, in profile and axial position of the calcaneus with infectious (osteomyelitis) or neoplastic (bone tumor or metastatic tumor) processes. Repeat radiographic examinations after last re-evaluation in 12 weeks.

19. Ultrasound examination of affected foot showing local infectious process of soft tissues, or neoplastic process of soft tissues. Repeat radiographic examinations after last re-evaluation in 12 weeks.

Date of first enrolment
18/04/2014

Date of final enrolment
01/04/2015

Locations

Countries of recruitment
Brazil

Study participating centre
Rua Borges Lagoa 778
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Sponsor information

Organisation
Funding Authority for Studies and Projects, Ministry of Science and Technology (Financiadora de Estudo e Projetos) (Brazil)

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Sponsor type
Government

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https://ror.org/030w99567

Funder(s)

Funder type
Government

Funder Name
Funding Authority for Studies and Projects, Ministry of Science and Technology (Financiadora de Estudo e Projetos) (Brazil); Ref. 1873/07 (Convênio 01.08.0524.00 - Encomenda Vertical de Projeto de Pesquisa)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration