

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

A comparison of shock wave versus corticosteroid for pain reduction in plantar fasciitis: randomized clinical trial

Protocol summary

Summary

Objective: to compare the clinical effectiveness of local corticosteroid injection with shock wave for plantar fasciitis. Inclusion criteria: more than 18 years of age; a history of heel pain for at least four weeks unresponsive to conservative treatments; pain with the intensity of more than 2 in a 100 mm visual analog scale at the baseline; tenderness at the medial plantar calcaneal region. Exclusion criteria: evidence of calcaneal fracture on x-ray; history of heel surgery; damage to Achilles tendon; inflammatory diseases; diabetes mellitus; local or systemic infections; peripheral vascular diseases; gout; blood coagulation disorders; corticosteroid injection during the last 6 months; contraindications to steroid; non-steroidal anti-inflammatory use within the last 7 days. Participants: overall, 74 patients are randomly allocated equally to two groups. Primary outcome: pain intensity at the standing position. Secondary outcomes: early morning pain; pain on joint movement, daily activities, climbing stairs and exercise tolerance. The outcomes are evaluated repeatedly up to 3 months after interventions. Interventions: in the group corticosteroid, a single dose of 40 mg methylprednisolone acetate (0.5 ml) mixed with 2 ml of 2% lidocaine is injected. For the group shock wave three doses of 2000 pulses of energy with 10 Hz frequency and 2.5 bar pressure with the intervals of one week are applied. Randomization and blinding: a computer-generated randomization list of 74 items in blocks of variable sizes is used. We had two groups of 37 participants each. The clinical assessor will be blinded to the baseline evaluations and to the administered treatments.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014030616865N1**

Registration date: **2014-05-19, 1393/02/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-19, 1393/02/29

Registrant information

Name

Mahsa Asheghan

Name of organization / entity

Baqiatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2013-07-01, 1392/04/10

Expected recruitment end date

2014-04-30, 1393/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of shock wave versus corticosteroid for pain reduction in plantar fasciitis: randomized clinical trial

Public title

A comparison of shock wave versus corticosteroid for pain reduction in plantar fasciitis: randomized clinical trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: more than 18 years of age; a history of heel pain for at least four weeks unresponsive to conservative treatments (NSAIDs); pain with the intensity of more than 2 in a 100 mm visual analog scale (VAS) at the baseline visit; tenderness at the medial plantar calcaneal region Exclusion criteria: evidence of calcaneal fracture on x-ray; history of heel surgery; damage to Achilles tendon; inflammatory diseases like rheumatoid arthritis; diabetes mellitus; local or systemic infections; peripheral vascular diseases; gout; blood coagulation disorders; corticosteroid injection during the last 6 months; contraindications to steroid injection; non-steroidal anti-inflammatory use within the last 7 days; Pregnant or breast feeding mothers

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Chamran highway

City

Tehran

Postal code

14455364

Approval date

2011-01-01, 1389/10/11

Ethics committee reference number

1032

Health conditions studied

1

Description of health condition studied

Plantar fascial fibromatosis

ICD-10 code

M72.2

ICD-10 code description

Plantar fascitiis

Primary outcomes

1

Description

Pain intensity at the standing position

Timepoint

All the outcomes were evaluated at the baseline visit and at 1 week, 1 month, and 3 months after the intervention.

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Early morning pain; pain on joint movement; daily activities; climbing stairs and exercise tolerance

Timepoint

All the outcomes were evaluated at the baseline visit and at 1 week, 1 month, and 3 months after the intervention.

Method of measurement

Visual analog scale. We also assess the ability to perform daily activities, climbing stairs and exercise tolerance with visual analog scale for foot and ankle (VASFA). Patients state their levels of functionality with matching it to the numbers 0 (unable to do) to 100 (without any difficulty).

Intervention groups

1

Description

For the group shock wave three doses of 2000 pulses of energy with 10 Hz frequency and 2.5 bar pressure with the intervals of one week are applied.

Category

Treatment - Drugs

2

Description

In the group corticosteroid, a single dose of 40 mg methylprednisolone acetate (0.5 ml) mixed with 2 ml of 2% lidocaine is injected.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Kamran Azma

Street address

Etemad Zadeh alley, Western Fatemi street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Baqiatallah University of Medical Sciences

Full name of responsible person

Morteza Izadi

Street address

Mollasadra street

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Baqiatallah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Baqiatallah University of Medical Sciences

Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty