Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

A prospective comparative study of Extracorporeal Shock Wave and Corticosteroid injection in the treatment of plantar fasciitis

Protocol summary

Summary

Plantar fasciitis is a painful condition caused by inflammation or degeneration of plantar fascia. In severe cases corticosteroid injection can lead to decreasing pain and increasing participation in rehabilitation programs. As this disorder, if not treated, can alter vocational and sport activities and because of possible side effects of corticosteroid injection, we decided to compare this treatment with shockwave therapy in the treatment of this disease. This is a randomized double blinded study in 74 patients. Inclusion criteria: age more than 18; Heel pain more than 4 weeks; nonresponsive to conservative treatments; pain intensity more than 2 in VAS. Exclusion criteria: heel surgery, corticosteroid injection in the last 6 months or NSAIDS consumption in the last 7 days. Intervention: 3 sessions of 2000 pulses, 2.5 bar 10 Hz shock wave therapy or 40 mg methyl prednisolone and 2 cc lidocain 2% injection. Primary outcome: decreased pain during standing and morning pain. Secondary outcome: ameliorating in ADL and sport activity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203069221N1**
Registration date: **2012-04-11, 1391/01/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-11, 1391/01/23

Registrant information

Name

Nafiseh Maleki

Name of organization / entity

Army University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8595 3476

Email address

dr_maleki@mut.ac.ir

Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A prospective comparative study of Extracorporeal Shock Wave and Corticosteroid injection in the treatment of plantar fasciitis

Public title

A comparative study of shock wave therapy and corticosteroid injection in the treatment of heel pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1.age more than 18; heel pain more than 4 weeks; nonresponsive to conservative treatments; pain intensity more than 2 in VAS; no evidence of calcaneal FX; patients be able to follow the study for 3 months after intervention. Exclusion criteria: heel surgery; nerve injury or achillis tendon injury. RA, DM, local infection, systemic infection, pripheral vascular

disease, coagulation disorders, CRPS, pregnancy, breast feeding, corticosteroid injection in the last 6 months or NSAIDS consumption in the last 7 days; history of sensitivity to injection solution.

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **74**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Army University of Medical Sciences

Street address
Fatemi ave., Etemadzadeh st.

City
Tehran

Postal code

Approval date
2011-11-06, 1390/08/15

Ethics committee reference number
1032

Health conditions studied

1

Description of health condition studied
plantar fasciitis

ICD-10 code
M72.2

ICD-10 code description
Fibroblastic disorders

Primary outcomes

1

Description
pain in standing and morning pain

Timepoint
before intervention ,1 week ,1 and 3 months after intervention

Method of measurement
visual analog scale (VAS) which is from 0 (no pain) to 10 (very severe pain)

Secondary outcomes

1

Description
ameliorating in ADL and sportive activity

Timepoint
befor intervention, 1 week, 1 and 3 months after intervention

Method of measurement
visual analog scale foot and ankle (VASFA) which is from 0 (compeletly impaired) to 100(normal)

Intervention groups

1

Description
3 sessions of 2000 pulses, 2.5 bar 10 Hz shock wave therapy

Category
Treatment - Other

2

Description
40 mg of methyl prednisolone and 2 cc lidocain 2% injection

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
501 hospital

Full name of responsible person

Street address

City
Tehran

2

Recruitment center

Name of recruitment center
Firouzgar hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Army University of Medical Sciences
Full name of responsible person
Zahra Reza soltani
Street address
Fatemi ave., Etemad zadeh st.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Army 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
Army University of Medical Sciences
Full name of responsible person
Nafiseh Maleki
Position
Resident
Other areas of specialty/work
Street address
Fatemi ave .Etemadzadeh st
City
Tehran
Postal code
Phone
+98 21 8595 3476
Fax
Email
mnafism@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Army University of Medical Sciences
Full name of responsible person
Nafiseh Maleki
Position
Resident
Other areas of specialty/work
Street address
Fatemi ave .Etemadzadeh st
City
Tehran
Postal code
Phone
+98 21 8595 3476
Fax
Email
mnafism@yahoo.com
Web page address

Person responsible for updating data

Contact

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