

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of therapeutic responses of corticosteroid injection vs Extra-corporeal shock-wave treatment in patients with acute plantar fasciitis referred to Rasht Poursina hospital

Protocol summary

Summary

(1) Objectives: This study seeks to evaluate therapeutic responses of these methods in patients with acute plantar fasciitis. (2) Design: Randomized clinical trial. (3) Setting and conduct: after randomization using random block system, in control group, 1 c.c of "Methyl-prednisolone acetate" 40 milligrams plus 1 c.c of "lidocaine" 2% will be injected in maximal point tenderness of inferomedial aspect of calcaneal tuberosity. For all intervention group patients, three sessions of shock-wave with 1500-2000 frequency and energy density of 0.15 mJ/mm² with 1 week interval (total energy flux density dose: 900 mJ/mm²) will be performed. (4) Participants including major eligibility criteria: All patients > 18 years old with clinical acute plantar fasciitis diagnosis; Severe morning calcaneal pain which ameliorates after walking; Point tenderness on calcaneal tuberosity. Exclusion criteria: History of rheumatoid arthritis; Psycho-social problems; Diabetes mellitus; History of local injection and physiotherapy; any bony lesion including fractures or tumors. (5) Intervention: Intervention group: Corticosteroid injection, Control group: intermediate Extra-corporeal Shock-wave treatment (ESWT) (6) Main outcome measures: Measuring alteration of pain recorded in VAS score

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108097274N1**
Registration date: **2011-08-28, 1390/06/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-08-28, 1390/06/06

Registrant information

Name

Mohsen Mardani Kivi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1321 1470

Email address

mardani@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2011-07-23, 1390/05/01

Expected recruitment end date

2012-01-21, 1390/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic responses of corticosteroid injection vs Extra-corporeal shock-wave treatment in patients with acute plantar fasciitis referred to Rasht Poursina hospital

Public title

Comparison of therapeutic responses of corticosteroid injection vs ultrasound in patients with plantar fasciitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: All patients with plantar fasciitis or calcaneal spur diagnosis referred to orthopedic clinic of Poursina Hospital in Rasht; Severe morning calcaneal pain which ameliorates after walking; Point tenderness on calcaneal tuberosity. Exclusion criteria: History of rheumatoid arthritis; Psycho-social problems; Diabetes mellitus; History of local injection and physiotherapy; Any bony lesion including fractures or tumors.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 68

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Guilan University of Medical Sciences

Street address

Vice chancellor for research, Guilan University of Medical Sciences, Namjou avenue

City

Rasht

Postal code

Approval date

2011-07-20, 1390/04/29

Ethics committee reference number

1900189603

Health conditions studied

1

Description of health condition studied

Plantar fasciitis

ICD-10 code

M72.2

ICD-10 code description

Plantar fascial fibromatosis Plantar fasciitis

Primary outcomes

1

Description

Therapeutic response (Rate of pain reduction)

Timepoint

Pre-treatment, 3, 6 and 12 weeks post-treatment

Method of measurement

VAS score

Secondary outcomes

1

Description

Recurrence rate

Timepoint

Recurrence rate

Method of measurement

VAS score

Intervention groups

1

Description

For all intervention group patients, three sessions of shock-wave with 1500-2000 frequency and energy density of 0.15 mJ/mm² with 1 week interval (total energy flux density dose: 900 mJ/mm²) will be performed

Category

Treatment - Devices

2

Description

The orthopedist needles and injects mixture of 1cc of Methyl Prednisolon Acetate (40mg) and 1cc of 2% Lidocaine at maximal point tenderness from inferomedial aspect of calcaneal tuberosity in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam-Reza Clinic of Poursina Hospital

Full name of responsible person

Dr Mohsen Mardani Kivi

Street address

Imam-Reza clinic, Poursina hospital, Parastar avenue

City
Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr. Abdolrasoul Sobhani, Research chancellor of Guilan university of medical science

Street address

Vice chancellor for research, Guilan University of Medical Sciences, Namjou avenue

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Guilan 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

Guilan University of Medical Science

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Assistant Professor

Other areas of specialty/work

Street address

Orthopedic Department, Poursina Hospital, Parastar avenue.

City

Rasht

Postal code

Phone

+98 13 1321 1470

Fax

Email

mardani@gums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Assistant Professor

Other areas of specialty/work

Street address

Orthopedic Department, Poursina Hospital, Parastar avenue

City

Rasht

Postal code

Phone

+98 13 1321 1470

Fax

Email

mardani@gums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr. Mohsen Mardani Kivi

Position

Orthopedic Surgeon, Assistant Professor

Other areas of specialty/work

Street address

Orthopedic Department, Poursina Hospital, Parastar avenue

City

Rasht

Postal code

Phone

Fax

Email

mardani@gums.ac.ir

Web page address

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