

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effectiveness of high energy radial extra corporeal shock wave therapy (ESWT) versus local corticosteroid injection in the treatment of chronic plantar fasciitis, a single blinded randomized clinical trial.

Protocol summary

Summary

Objectives: evaluation effectiveness of high energy radial extra corporal shock wave therapy (ESWT) in the treatment of chronic plantar fasciitis and comparing it with local injection of corticosteroid. Design: 40 patients with complaint of heel pain for more than 2 months and diagnosis of chronic plantar fasciitis during one-year are selected. Setting and conduct: The eligible patients will be divided to 2 groups of 20 , A & B, via closed envelopes method. Inclusion criteria: patients with heel pain for more than 2 months. Exclusion criteria: 1. History of systemic inflammatory diseases, 2. Infective or malignant diseases, 3. History of direct trauma with or without foot bones fracture, 4. Previous physiotherapy in the past 3 months or local steroid injection in the past 6 months, 5. Heel pain related to Achilles bursitis, 6. Presence of myofascial pain syndrome and trigger points in gastrocnemius muscle, 7. Active S1 radiculopathy. Interventions: In group A (shockwave therapy), high energy radial ESWT with energy flux intensity of 0.25 mj /mm2, 2000 impulse, 10 Hz frequency, for 5 sessions twice a week will be applied. In group B, local injection of 40 mg Triamcinolone to tender point of heel will be done only one session. Moreover, therapeutic foot insoles will be prescribed in both groups and stretching exercises for medial fascia as well as gastrocnemius muscles will be educated. Main outcome measurements: Evaluation of pain intensity is done using visual analogue scale, so that patients must have at least 20 mm pain score. Assessment of foot function will be done using foot function index. Third variable is satisfaction of treatment at the end of intervention by satisfaction rating scale. These variables will be assessed at baseline, weeks 4 and 8 after treatment and finally will be analyzed and compared between groups statistically.

General information

Acronym

ESWT: extracorporeal shock wave therapy.

IRCT registration information

IRCT registration number: **IRCT201306163217N7**

Registration date: **2014-03-04, 1392/12/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-03-04, 1392/12/13

Registrant information

Name

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Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Physical medicine and rehabilitation research center, Vice chancellor for research, Tabriz University of Medical Sciences.

Expected recruitment start date

2013-11-22, 1392/09/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of high energy radial extra corporeal shock wave therapy (ESWT) versus local corticosteroid injection in the treatment of chronic plantar fasciitis, a single blinded randomized clinical trial.

Public title

Comparison of high energy radial extra corporeal shock wave therapy with local corticosteroid injection in the treatment of plantar fasciitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all of patients with chronic plantar fasciitis and heel pain and local tenderness for more than 2 months. Exclusion criteria: 1) History of systemic inflammatory diseases. 2) Infective or malignant diseases. 3) History of direct trauma with or without foot bones fracture. 4) Previous physiotherapy in the past 3 months or local steroid injection in the past 6 months. 5) Active S1 radiculopathy (which could be justify the cause of plantar fascia pain). 6) Heel pain related to Achilles bursitis. 7) Presence of myofascial pain syndrome and trigger points in gastrocnemius muscle.

AgeFrom **20 years** old to **65 years** old**Gender**

Both

Phase

2

Groups that have been masked*No information***Sample size**Target sample size: **40****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

Patients will be randomly divided to two groups via closed envelopes method.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz university of medical science committee of ethics.

Street address

3rd floor- Number 2 Central Building - Tabriz university of medical science - Golgasht Avenue

City

Tabriz

Postal code

51656

Approval date

2013-11-18, 1392/08/27

Ethics committee reference number

5/4/7049

Health conditions studied**1****Description of health condition studied**

chronic plantar fascitis

ICD-10 code

M72.2

ICD-10 code description

Fibroblastic disorder, plantar fascial fibromatosis, plantar fasciitis.

Primary outcomes**1****Description**

pain intensity

Timepoint

Before treatment and 4 & 8 weeks after treatment

Method of measurement

Visual Analogue Scale with 0-100mm grading.

2**Description**

Daily foot functional ability

Timepoint

Before treatment and 4 & 8 weeks after treatment

Method of measurement

Questionnaire of foot function index.

3**Description**

satisfaction rate

Timepoint

at the end of intervention

Method of measurement

satisfaction rating scale in according 4 grades:Excellent, good, moderate and poor.

Secondary outcomes

empty

Intervention groups

1

Description

Radial extracorporeal shock wave.Using high energy radial shock wave with energy flux intensity of 0.25mj/mm2 , 2000 impulse (4Bar) and frequency of 10 HZ twice a week for five sessions.

Category

Treatment - Devices

2

Description

One local injection of 40 mg triamcinolone in tender point of medial zone of heel. (Amp triamhexal. made by Germany)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital of Tabriz

Full name of responsible person

Faraz Notghi

Street address

Daneshgah Ave.

City

East Azarbaijan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of medical science

Full name of responsible person

Dr. Yaghoob Salek Zamani

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3rd floor- Number 2 Central Building - Tabriz
University of Medical Sciences- Golgasht Avenue
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City

tabriz

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, Tabriz University of medical science

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

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Full name of responsible person

Faraz Notghi

Position

Resident of physical medicine and rehabilitation

Other areas of specialty/work

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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