Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 envelops 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.
Age
From **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 envelops 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
Street address
3rd floor- Number 2 Central Building - Tabriz University of Medical Scineces- Golgasht Avenue Tabriz
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
Tabriz university of medical science
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Faraz Notghi
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Person responsible for updating data

Contact

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Associate professor of physical medicine and rehabilitation

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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