

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of The Therapeutic Effects of Ultrasound-guided Dextrose Prolotherapy Injection with Shock wave Therapy in the Treatment of Plantar Fasciitis

Protocol summary

Study aim

To compare the clinical effectiveness of local dextrose injection with shock wave for plantar fasciitis

Design

A total number of 7 patients will randomly be categorized into one of the following groups, using block randomization (39 patients in each group): Group A: Will receive ultrasound guided localized injection of 2 ml Dextrose 20% in the attachment of the plantar fascia to the calcareous bone. Group B: Will receive 3 sessions of shock wave therapy every other day for 2000 pulse, 2 Hz with power of 0.2 mj/mm2.

Settings and conduct

This randomized control trial will be conducted in Baghiatolah Azam Hospital, Tehran, Iran. This hospital is affiliated to the Baghiatolah university of medical sciences. Based on the nature of the interventions, blinding is not applicable for this study.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 20 to 50 years; A typical history of plantar fasciitis and localized tenderness in the medial side of the heel; providing informed consent for participation in the study. 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

Intervention groups

Overall, 78 patients will randomly be allocated equally into two groups

Main outcome variables

Pain intensity at the standing position; 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.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140306016865N2**

Registration date: **2019-07-31, 1398/05/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-31, 1398/05/09**

Update count: **0**

Registration date

2019-07-31, 1398/05/09

Registrant information

Name

Mahsa Asheghan

Name of organization / entity

Baqiatallah University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-31, 1398/05/09

Expected recruitment end date

2019-10-31, 1398/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of The Therapeutic Effects of Ultrasound-guided Dextrose Prolotherapy Injection with Shock wave Therapy in the Treatment of Plantar Fasciitis

Public title
Dextrose Prolotherapy Injection in the Plantar Fasciitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 50 years A typical history of plantar fascistic and localized tenderness in the medial side of the heel providing informed consent for participation in the study.
Exclusion criteria:

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be categorized into one of the following groups, using block randomization: Group A: Receive ultrasound guided localized injection of 2 ml Dextrose 20% in the attachment of the plantar fascia to the calcareous bone. Group B: Receive 3 sessions of shock wave therapy every other day for 2000 pulse, 2 Hz with power of 0.2 mj/mm2

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
Baghiatolah University of Medical Sciences (BMSU)
Street address
Baghiatolah University of Medical Sciences, Mola

Sadra St, Vanak SQ, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1435915371
Approval date
2019-01-20, 1397/10/30
Ethics committee reference number
IR.BMSU.REC.1397.138

Health conditions studied

1

Description of health condition studied
Plantar fascial fibromatosis
ICD-10 code
M72.2
ICD-10 code description
Plantar fascial fibromatosis

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 FAAM Questionnaire.

Intervention groups

1

Description
Intervention group: Will receive ultrasound guided localized injection of 2 ml Dextrose 20% in the attachment of the plantar fascia to the calcareous bone.
Category
Treatment - Drugs

2

Description

Control group: Will receive 3 sessions of shock wave therapy every other day for 2000 pulse, 2 Hz with power of 0.2 mj/mm2

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

baghiatolah hospital

Full name of responsible person

Dr. Mahsa Asheghan

Street address

baghiatolah hospital; Mola Sadra St; Vanak SQ;
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Morteza Izadi

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mahsa Asheghan

Position

Assistant professor of physical medicine and rehabilitation

Latest degree

Specialist

Other areas of specialty/work

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Position

Assistant professor of physical medicine and rehabilitation

Latest degree

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The study will be published in an article.

When the data will become available and for how long

just after publication.

To whom data/document is available

researchers

Under which criteria data/document could be used

for research purpose

From where data/document is obtainable

From the indexing journal website.

What processes are involved for a request to access data/document

The researcher must download the article.

Comments