Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 fascitis

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 Baghaiatolah 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 fascistic 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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
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1435916471
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hospital.research2@gmail.com
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
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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