Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Ultrasound-guided Prolotherapy, Oxygen-ozone and corticosteroid injection for the treatment of plantar fasciitis: A randomized, double-blind, multi-center study.

Protocol summary

Study aim

To compare effect of ultrasound guided Corticosteroid, Ozone and Dextrose injection in patients with Plantar fasciitis.

Design

A phase 3, umulticenteral, randomized, double blinded, clinical trial with a parallel group, and one week and two months followed ups. 1 cc lidocaine 2% will be used for local anesthesia (skin) in all groups. Then, under sterile condition, one group will be received ultrasound guided Ozone injection from medial heel with 25G needle. Other groups will receive corticosteroid or dextrose prolotherapy.

Settings and conduct

patients with plantar fasciitis referred to physiatrists clinics in Iran and Tabriz (University of Medical Sciences)

Participants/Inclusion and exclusion criteria

Inclusion criteria: More than three months of heel pain which is worst with the first few steps after awakening. Pain and tenderness by palpation of the medial calcaneal or the proximal plantar fascia. VAS greater or equal to 4. Sonographic plantar fascia thickness greater than 4 mm with hypoechoic change. Exclusion criteria: History of ankle or calcaneal trauma. Positive Tinel's sign on the tibial nerve. History of systemic inflammatory or connective tissue disease. History of lumbar disc herniation with S1 radiculopathy. History of gout. Uncontrolled diabetes. History of heel surgery or injections in the last six months. Cystic or mass lesion at the site of the painful heel. History of paresthesia, numbness or peripheral neuropathy. Coagulation disorder. Pregnancy. Allergic reaction to Corticosteroid or Dextrose or Ozone. Infection at the injection site. Initiation of PF treatment within 10 days before intervention such as NSAIDs or physical therapy. History of vascular insufficiency causing heel pain.

Intervention groups

Three ultrasound guided injection groups : 1.Corticosteroid, 2.Ozone 3.Dextrose

Main outcome variables

Visual Analogue Scale, Foot and Ankle Ability Measure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151017024572N24**
Registration date: **2020-08-14, 1399/05/24**
Registration timing: **prospective**

Last update: **2020-08-14, 1399/05/24**
Update count: **0**

Registration date

2020-08-14, 1399/05/24

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-20, 1399/06/30

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ultrasound-guided Prolotherapy, Oxygen-ozone and corticosteroid injection for the treatment of plantar fasciitis: A randomized, double-blind, multi-center study.

Public title

Ultrasound-guided Prolotherapy, Oxygen-ozone and corticosteroid injection for the treatment of plantar fasciitis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

More than three months of heel pain (in medial aspect) which is worst with the first few steps after awakening. Pain and tenderness elicited by palpation of the medial calcaneal or the proximal plantar fascia. Visual analog scale (VAS) score greater than or equal to 4. Sonographic plantar fascia thickness greater than 4 mm with hypoechoic change at insertion point to the calcaneus.

Exclusion criteria:

History of ankle or calcaneal trauma. Positive Tinel’s sign on the tibial nerve (posterior to medial malleoli). History of systemic inflammatory or connective tissue disease such as rheumatoid arthritis. History of lumbar disc herniation with S1 radiculopathy. History of gout. Uncontrolled diabetes. History of heel surgery or injections in the last six months. Cystic or mass lesion at the site of the painful heel. History of paresthesia, numbness or peripheral neuropathy. Coagulation disorder. Pregnancy. Allergic reaction to Corticosteroid or Dextrose or Ozone. Infection at the injection site. Posterior heel pain. Initiation of PF treatment within 10 days before intervention such as anti-inflammatory drug therapy, physical therapy. History of vascular insufficiency causing heel pain.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly divided into three treatment groups using a table of random numbers and a centralized randomization method. In order to execute the randomization process to create a random sequence and to perform the random allocation process we will use Random Allocation Software (RAS) which will be created by statistician. Numbers created with software will be exported to the table by the statistician. Because there are more than one center for this multi-central research and for correct allocation of participants to the study groups, two hours before the patient's visit for injection, the person responsible for injection will contact the statistician by phone or text message and will ask her about the random assignment of the participant to a specific group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The injection material is prepared in the syringe without informing the patient and the syringes will be covered with an aluminum foil so that the participant does not know the type of injection material. Patients will be prohibited from receiving any NSAIDs or analgesics for a 15-day wash-out period prior to enrollment and intervention. Due to the different nature of ozone (gas), during the injection, there is a possibility that the injector will notice the nature of the substance under sonography. The person responsible for outcome measures and the person responsible for the statistical analysis are also kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Next to Milad Tower, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-01-19, 1398/10/29

Ethics committee reference number

IR.IUMS.REC.1398.1106

Health conditions studied

1

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

Primary outcomes

1

Description
Pain
Timepoint
Before intervention, 1 and 8 weeks after intervention
Method of measurement
Visual Analogue Scale Questionnaire

Secondary outcomes

1

Description
Foot and Ankle Ability Measure (FAAM)
Timepoint
Before intervention, 1 and 8 weeks after intervention
Method of measurement
Foot and Ankle Ability Measure (FAAM) Questionnaire

Intervention groups

1

Description
Intervention group one: Corticosteroid, 40 mg Methylprednisolone, one time injection at the site of plantar fascia insertion
Category
Treatment - Other

2

Description
Intervention group two: Ozone (O2-O3), 12 micro-gram, one time injection at the site of plantar fascia insertion
Category
Treatment - Other

3

Description
Intervention group three: Prolotherapy (Dextrose 20 %), one time injection at the site of plantar fascia insertion
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital, Iran University of Medical Sciences, Neuromusculoskeletal Research Center
Full name of responsible person
Arash Babaei-Ghazani
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Dr. Arash Babaei

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Data will only be provided for journal during manuscript submission or for meta-analysis at the specific request of other individuals.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

There is no further information

When the data will become available and for how

long

There is no further information

To whom data/document is available

There is no further information

Under which criteria data/document could be used

There is no further information

From where data/document is obtainable

There is no further information

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

There is no further information

Comments