Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of ultrasound guided local injections of ozone and corticosteroid efficacy on pain and daily activity of patients with chronic plantar fasciitis

Protocol summary

Summary

In this study we compare effects of ozone and corticosteroid on pain and daily activity of patients with plantar fasciitis. Patients suffering from heel pain with a VAS(Visual Analogue Scale) more than 4 for at least two months whose history, physical exam and sonography confirm plantar fasciitis are included. Patients will be randomized with a simple randomization method in two intervention groups. One group will be injected with 2 cc of ozone 20 ug 20% and the other with a combination of 1 cc of methylprednisolone 40 mg and 1 cc of saline 0.9%, both in plantar fascia under an ultrasound guide. Anesthesia will be induced by 1 cc of lidocaine 1% and a 22 gauged needle. A resident of physical medicine and rehabilitation who is blind toward the injected drugs will evaluate the patients at the base time, 2 weeks and 8 weeks following the injection. The evaluation will be done for efficacy on pain by VAS and on daily activity by Foot and Ankle Ability Measure (FAAM) questionnaire. Thickness of plantar fascia will be determined by sonography. Finally the collected data from two groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017022124572N5**
Registration date: **2017-07-13, 1396/04/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-07-13, 1396/04/22

Registrant information

Name
Arash Babaei-Ghazani
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Iran University Of Medical Science, Dr Eftekhar Ardebili

Expected recruitment start date

2017-04-12, 1396/01/23

Expected recruitment end date

2017-04-23, 1396/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ultrasound guided local injections of ozone and corticosteroid efficacy on pain and daily activity of patients with chronic plantar fasciitis

Public title

Effects of ozone and corticostroid on plantar fasciitis treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: History of plantar fasciitis, Patients suffering from heel pain with a VAS (Visual Analogue

Scale) more than 4 for at least two months whose history, physical exam and sonography confirm plantar fasciitis. Exclusion criteria: A history of direct trauma; systemic inflammatory or soft tissue diseases; disk herniation with S1 radiculopathy; gout; diabetes mellitus; surgery or injection in fascia since 6 months ago, existence of cyst/mass in pain site; coincidence of paresthesia or numbness; coagulopathy; pregnancy; hypersensitivity to corticosteroids; infection of injection site, posterior heel pain and any treatment for the condition since 4 weeks ago; physiotherapy, splint, iontophoresis, iontophoresis, and shock-wave in the last 2 months.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Iran University Of Medical Sience

Street address
Iran University Of Medical Science, Hemmat Freeway, next to Milad Hospital

City
Tehran

Postal code

Approval date
2017-04-12, 1396/01/23

Ethics committee reference number
IR.IUMS.REC 1395 .28053

Health conditions studied

1

Description of health condition studied
Plantar fasciitis

ICD-10 code
XIII

ICD-10 code description
Diseases of the musculoskeletal system and connective tissue

Primary outcomes

1

Description
pain

Timepoint
Before injection, 2 weeks and 8 weeks after injection

Method of measurement
Visual Analog Scale(VAS)

Secondary outcomes

1

Description
Thickness of plantar fascia

Timepoint
before injection, 2 weeks and 8 weeks after injection

Method of measurement
sonography

2

Description
Thickness of plantar fascia

Timepoint
before injection, 2 weeks and 8 weeks after injection

Method of measurement
sonography

Intervention groups

1

Description
First intervention group: injection 0f a combination of 1 cc methylprednisolone 40 mg and 1 cc salin 0.9%

Category
Treatment - Drugs

2

Description
Second intervention group: injection of 2 cc of ozone 20ug

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar Hospital
Full name of responsible person
Neda karimi
Street address
Behafarin Ave, Valiasr Square
City
tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Iran University Of Medical Science
Full name of responsible person
Dr Eftekhar Ardebili
Street address
Next to Milad hospital, Hemmat Autobahn
City
Tehran
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 of Iran 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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Web page address

Person responsible for updating data

Contact

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