

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Sep 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 8991

Email address

babaei-ghazani.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

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

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 Of 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

Street address

Firoozgar hospital, Behafarin Avenue, Valiasr Square

City

Tehran

Postal code

Phone

+98 21 8894 2970

Fax

Email

Karimi.neda367@gmail.com

Web page address

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

Firoozgar hospital

Full name of responsible person

Neda karimi

Position

Resident of physical medicine and rehabilitation

Other areas of specialty/work

Person responsible for scientific inquiries

Contact

Name of organization / entity

Firoozgar Hospital

Full name of responsible person

Dr Arash Babaei

Position

Assistance professor of physical medicine and rehabilitation

Other areas of specialty/work

Street address

Firoozgar hospital, Behafarin Avenue, Valiasr Square

City

Tehran

Postal code

Phone

+98 21 8894 2970

Fax

Email

Babaei-ghazani.a@iums.ac.ir

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