

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the efficacy of local corticosteroid injection with percutaneous fasciotomy and ozone in the treatment of plantar fasciitis

Protocol summary

Study aim

Determining the effect of local corticosteroid injection along with percutaneous fasciotomy compared to local ozone injection in patients with plantar fasciitis

Design

Clinical trial, with parallel groups, double-blind, randomized, phase 2 on 40 patients, rand function of Excel software was used for randomization.

Settings and conduct

The aim of this study is to evaluate therapeutic response of ozone injection and local corticosteroid injection and fasciotomy in treatment of plantar fasciitis. to do so, 40 patients referring to Tabriz shahid madani hospital with diagnosis of plantar fasciitis will be included to the study. The patients of each group are unaware of the treatment of the other group, and the analyst will not be aware of the type of treatment in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients with plantar fasciitis who have not responded to routine medical treatments for more than a month. Exclusion criteria: history of RA; history of direct trauma; history of local injection or physical therapy in the last 3 months' pain behind the heel related to Achilles bursitis and...; active S1 radiculopathy; the presence of trigger points in the calf muscles.

Intervention groups

The group that receives corticosteroid injection. The group that is subjected to ozone injection

Main outcome variables

Pain relief; improvement of function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220614055168N1**

Registration date: **2022-12-20, 1401/09/29**

Registration timing: **prospective**

Last update: **2022-12-20, 1401/09/29**

Update count: **0**

Registration date

2022-12-20, 1401/09/29

Registrant information

Name

Sina Nasirzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3177 1041

Email address

nasirzadeh89a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-15, 1401/10/25

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of local corticosteroid injection with percutaneous fasciotomy and ozone in the treatment of plantar fasciitis

Public title

Corticosteroid in plantar fasciitis "Effect of ozone in the treatment of plantar fasciitis"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with plantar fasciitis with local pain and sensitivity of the soles of the feet or heels, especially in the morning, who have not responded to routine medical treatments for more than a month, are included in the study with informed consent.

Exclusion criteria:

History of systemic inflammatory disease such as RA
History of direct trauma with and without fractures of the plantar bones
History of local injection or physical therapy in the last 3 months
pain in posterior heel associated with Achilles bursitis
The presence of S1 active radiculopathy, which mainly explains the cause of plantar fascia pain
The presence of trigger points in the calf muscles

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 40

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients of each group are unaware of the treatment of the other group, and the analyst will not be aware of the type of treatment in the groups. The randomization of the patient is such that the patient randomly chooses one of the ozone or corticosteroid drugs for injection. This is implemented in such a way that two packages containing the names of each of the treatment methods are provided to the patient and the patient chooses one of them without knowing the contents of the package, yet the type of treatment is given to the patient. will be announced.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Golgasht Ave., Azadi Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2022-07-12, 1401/04/21

Ethics committee reference number

IR.TBZMED.REC.1401.315

Health conditions studied

1

Description of health condition studied

Plantar fasciitis

ICD-10 code

M72.2

ICD-10 code description

Plantar fascial fibromatosis

Primary outcomes

1

Description

Plantar pain score (VAS)

Timepoint

At the time of treatment, 4 weeks and 8 weeks after treatment

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: topical corticostroid as 40 mg methylprednisolone which is going to be injected once at the site of plantar fascia. percutaneous fasciotomy is going to be done in the session of corticosteroid injection therapy.

Category

Treatment - Drugs

2

Description

Intervention group: topical Ozone, 3cc, injected once at the site of plantar fascia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani hospital

Full name of responsible person

Mohammad Rahbar MD

Street address

Madani hospital, Daneshgah Ave., 29 Bahman Blvd.,
Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5163639889

Phone

+98 41 3445 5893

Email

nasirzadeh89a@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Rahbar MD

Street address

Tabriz University of Medical Sciences, Golgasht Ave.,
Azadi Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

1561661885

Phone

+98 41 3335 5921

Email

info@tbzmed.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Rahbar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Tabriz University of Medical Sciences, Golgasht Ave.,
Azadi Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5163639889

Phone

+98 41 3335 5921

Email

rahbarm@tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Rahbar

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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Tabriz

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East Azarbaijan

Postal code

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Phone

+98 41 3335 5921

Email
rahbarm@tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Sina Nasirzadeh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Tabriz University of Medical Sciences, Golgasht Ave.,
Azadi Blvd.

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Phone

+98 41 3445 5893

Email

nasirzadeh89a@gmail.com

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

Publishable articles from data results

When the data will become available and for how long

End of the study

To whom data/document is available

All researchers and clinical specialists

Under which criteria data/document could be used

Based on the criteria of the Ministry of Health in clinical trials

From where data/document is obtainable

Research vice of Tabriz University of Medical Sciences

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

There is no further information

Comments