

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

Registration timing: **prospective**

#### Study aim

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

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

Update count: **0**

#### Registration date

2022-12-20, 1401/09/29

#### Design

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

#### Registrant information

##### Name

Sina Nasirzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3177 1041

##### Email address

nasirzadeh89a@gmail.com

#### 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.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### 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.

#### 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

#### Intervention groups

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

#### Main outcome variables

Pain relief; improvement of function

#### Scientific title

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

#### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20220614055168N1**

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

#### 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

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##### 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

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## 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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**Email**

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**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**

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**Phone**

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**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**