# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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
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## Sponsors / Funding sources

**1**

**Sponsor**
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**Full name of responsible person**
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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**
Assisstant professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Physical Medicine
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## Person responsible for scientific inquiries

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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

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## 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**