

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy of prolotherapy vs. methylprednisolone acetate injection in the treatment of chronic plantar fasciitis

#### Protocol summary

##### Summary

The objective of this randomized, single blind trial is to investigate the effect of efficacy of prolotherapy vs. methylprednisolone acetate injection in the treatment of plantar fasciitis. In this study, 30 patients aged 18-70 years old with clinical diagnosis of plantar fasciitis in the past 6 months who meet the inclusion/exclusion criteria will be recruited and randomly assigned into intervention or control group. The patients in the intervention group will receive 1 ml of 2% lidocaine (20 mg/ ml) and 1 ml of 50% dextrose (25 g/50 ml) (dextrose monohydrate 500 mg) giving a 25% dextrose solution. Injection is performed through tender point with a rigid 27G needle. The patients in the control group will receive 1 ml steroid solution injection contained 40mg/ml methylprednisolone and 1 ml of 2% lidocaine. Pain intensity is measured before and 2 and 6 weeks following treatment by Visual Analogue Scale (VAS) and compared between the groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201108157323N2**

Registration date: **2011-11-15, 1390/08/24**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2011-11-15, 1390/08/24

##### Registrant information

##### Name

Mohsen Tajalli

##### Name of organization / entity

Shiraz University of Medical Sciences and Health

Services

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1231 9040

##### Email address

tajallim@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

medical university of shiraz

##### Expected recruitment start date

2011-10-07, 1390/07/15

##### Expected recruitment end date

2012-02-04, 1390/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of prolotherapy vs. methylprednisolone acetate injection in the treatment of chronic plantar fasciitis

##### Public title

Efficacy of dextrose 25% injection vs. steroid injection in the treatment of heel spur

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age 18-70 years old, clinical diagnosis of plantar fasciitis in the past 6 months, Diagnosis of plantar fasciitis was on the basis of pain at, or around, the plantar surface of the heel or the medial longitudinal arch, Exclusion criteria: chronic plantar fasciitis with systemic symptoms, evidence of pathologic disorders in laboratory data or radiograph of foot, steroid or prolotherapy drug solution injection in 3 months prior to

the study, severe co-existing disease such as diabetes, inflammatory arthritis or previous foot surgery

### Age

From **18 years** old to **70 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)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shiraz University of Medical Sciences and Health Services

##### Street address

Zand avenue

##### City

Shiraz

##### Postal code

#### Approval date

2011-10-06, 1390/07/14

#### Ethics committee reference number

CT-90-2112

## Health conditions studied

### 1

#### Description of health condition studied

plantar fasciitis

#### ICD-10 code

M72.2

#### ICD-10 code description

plantar fasciitis

## Primary outcomes

### 1

#### Description

pain intensity

#### Timepoint

before intervention; 2 and 6 weeks after intervention

#### Method of measurement

Visual Analogue ScaLe(VAS)

## Secondary outcomes

### 1

#### Description

side effects

#### Timepoint

second and sixth weeks

#### Method of measurement

examination, side effects such as rupture of ligament, heel pad atrophy, hypopigmentation

## Intervention groups

### 1

#### Description

Control Group : A 2.5 ml syringe is filled with 1 ml steroid solution injection contained 40mg/ml methylprednisolone and 1 ml of 2% lidocaine.

#### Category

Treatment - Other

### 2

#### Description

prolotherapy Group: A 2.5 ml syringe is filled with 1 ml of 2% lidocaine (20 mg/ ml) and 1 ml of 50% dextrose (25 g/50 ml) (dextrose monohydrate 500 mg) giving a 25% dextrose solution. Injection is performed through tender point with a rigid 27G needle .

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rehabilitation ward, Shahid Chamran Hospital

##### Full name of responsible person

Dr. Mohsen Tajalli

##### Street address

Chmran avenue

##### City

Shiraz

### 2

#### Recruitment center

##### Name of recruitment center

Rehabilitation ward, Shahid Dr. Fahgehi Hospital

**Full name of responsible person**

Dr. Mohsen Tajalli

**Street address**

Zand avenue

**City**

Shiraz

**3****Recruitment center****Name of recruitment center**

Rehabilitation ward, Hafez Hospital

**Full name of responsible person**

Dr. Mohsen Tajalli

**Street address**

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**City**

Shiraz

**4****Recruitment center****Name of recruitment center**

Rehabilitation ward, Shahid Motahari Hospital

**Full name of responsible person**

Dr. Mohsen Tajalli

**Street address**

Namazi square

**City**

Shiraz

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences and Health Services

**Full name of responsible person**

Kambiz Eskandari

**Street address**

Zand avenue

**City**

Shiraz

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz University of Medical Sciences and Health Services

**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**

Shiraz University of Medical Sciences and Health Services

**Full name of responsible person**

Dr. Mostafa Jazayeri Shoshtari

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**Web page address**

**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*