

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

15 Jun 2026

### Comparison of effectiveness between Corticosteroid and Hyaluronic acid injection in treatment of patients with Plantar fasciitis

#### Protocol summary

##### Study aim

Comparing the efficacy of injecting single dose of high-molecular-weight hyaluronic acid versus corticosteroid at the site of heel on pain, function, pressure pain threshold and thickness of plantar fascia among patients with plantar fasciitis

##### Design

Randomized double blind clinical trial with two parallel groups and 20 patients in each group. Randomization will be done by the means of table of random numbers.

##### Settings and conduct

In this study patients who are diagnosed with plantar fasciitis will be randomly allocated into two groups of 20 patients based on the table of random numbers. In one group high molecular weight hyaluronic acid and in the other group corticosteroid will be injected into the plantar fascia with the guide of ultrasound. The assessment of the pain, function, pressure pain threshold and the thickness of plantar fascia with ultrasound will be done before injection and 2 and 6 months after injection.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with plantar fasciitis, aged 25-60 years old who have not respond to initial conservative treatment. Non inclusion criteria: Pregnancy, Taking Corticosteroids (oral route) or in past 3 weeks or injecting corticosteroids at the site of plantar fascia in past 6 months, History of vasovagal syncope, Being hemodynamically unstable, Recent skin or soft tissue infection at the site of injection, Heel pain due to neuropathy or radiculopathy, History of Diabetes Mellitus, Fracture in surrounding bones, Having other diseases which can cause heel pain such as Ankylosing Spondylitis or other inflammatory disorders, History of surgery at Plantar Fascia

##### Intervention groups

A single injection of high-molecular-weight hyaluronic acid in one group and a single injection of corticosteroid in the other the heel.

##### Main outcome variables

pain, function, pressure pain threshold, the thickness of plantar fascia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130523013442N26**

Registration date: **2018-09-18, 1397/06/27**

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

Last update: **2018-09-18, 1397/06/27**

Update count: **0**

##### Registration date

2018-09-18, 1397/06/27

##### Registrant information

##### Name

Seyed Ahmad Raeissadat

##### Name of organization / entity

Modares Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2273 1112

##### Email address

a\_raeissadat@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-25, 1397/05/03

##### Expected recruitment end date

2018-10-27, 1397/08/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of effectiveness between Corticosteroid and Hyaluronic acid injection in treatment of patients with Plantar fasciitis

**Public title**  
Effect of Hyaluronic acid injection in treatment of Plantar fasciitis

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients with diagnosis of Plantar fasciitis who are visited at the Physical medicine & Rehabilitation clinic of Shahid Modarres hospital Age between 25-60 years old Having the pain since 3 months ago or more Not responding to initial conservative treatments such as shoe insoles, exercise and NSAIDs Willing to participate in the study  
**Exclusion criteria:**  
Pregnancy Taking Corticosteroids or NSAIDs (oral route) in past 3 weeks or injecting corticosteroids at the site of plantar fascia in past 6 months History of vasovagal syncope Being hemodynamically unstable Recent skin or soft tissue infection at the site of injection Heel pain due to neuropathy or radiculopathy History of Diabetes Mellitus Fracture in surrounding bones Having other diseases which can cause heel pain such as Ankylosing Spondylitis or other inflammatory disorders History of surgery at Plantar Fascia

**Age**  
From **25 years** old to **60 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **40**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients are randomly placed in two groups of receiving Hyaluronic acid or Corticosteroid injection by using table of random numbers

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
The participants are unaware of exact the type of the injected drug and since the physician who inject the drug and the one who follow up them are different, the later is blinded about the injected drug.

**Placebo**  
Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethic Committee of Shahid Beheshti University of Medical Sciences  
**Street address**  
Shahid Beheshti University of Medical Sciences, Shahid Arabi street, Yaman street, Shahid Chamran highway  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1958717443  
**Approval date**  
2018-07-25, 1397/05/03  
**Ethics committee reference number**  
IR.SBMU.MSP.REC.1397.403

## 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**  
heel pain

**Timepoint**  
Before intervention and 2 & 6 months after injection

**Method of measurement**  
Visual Analogue Scale questionnaire

## Secondary outcomes

**1**

**Description**  
Pressure Pain Threshold

**Timepoint**  
Before intervention and 2 & 6 months after injection

**Method of measurement**

Algometer

## 2

### **Description**

Effect of the pain on function

### **Timepoint**

Before intervention and 2 & 6 months after injection

### **Method of measurement**

Foot and Ankle Ability Measure (FAAM) questionnaire

## 3

### **Description**

Plantar fascia thickness in vertical and horizontal sections

### **Timepoint**

Before intervention and 2 & 6 months after injection

### **Method of measurement**

Ultrasound

## **Intervention groups**

### 1

#### **Description**

Intervention group: Injection of 1ml high molecular weight Hyaluronic acid 2% (trade name "Viscor", 2500-3500 kDa, Fermentation source, 50 mg in 2.5 cc, Made in Iran) and 1 ml Lidocaine 2%, injection in the heel , injection with the guide of ultrasound, single injection

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: Injection of 1 ml Methyl prednisolone acetate & 1 ml Lidocaine 2%, injection in the heel , injection with the guide of ultrasound, single injection

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Modarres Hospital

##### **Full name of responsible person**

Seyyed Ahmad Raeissadat

##### **Street address**

Saadat Abad street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1998734383

##### **Phone**

+98 21 2236 3244

#### **Email**

a\_raeissadat@sbmu.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Vice chancellor for research

##### **Street address**

Saadat Abad street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

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##### **Email**

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#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Mahtab Darvish

##### **Position**

Resident of Physical Medicine and Rehabilitation

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Physical Medicine

##### **Street address**

Pasdaran St.

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1953754163  
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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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**Position**  
Associate Professor of Physical Medicine and Rehabilitation department, Shahid Beheshti University of  
**Latest degree**  
Specialist  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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mahtab.darvish@sbm.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available