

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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@sbmu.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

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Saadat Abad street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice chancellor for research

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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

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Person responsible for scientific inquiries

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Name of organization / entity
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Associate Professor of Physical Medicine and Rehabilitation department, Shahid Beheshti University of
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Person responsible for updating data

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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