Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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, excercise 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 Hyalorunic 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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