

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the effect of ultrasound guided prolotherapy and ultrasound guided corticosteroid injection on pain score and foot function in patients with plantar fasciitis.

Protocol summary

Study aim

Comparison of the effectiveness of the two methods of ultrasound guided injection of corticosteroid or prolotherapy on the pain score and foot function in patients with plantar fasciitis to detect the more effective method.

Design

Parallel group randomized clinical trial with blinded participant and operator on 44 patients. Block randomization is implicated.

Settings and conduct

The clinical trial will be done on patients with plantar fasciitis who present to the Imam Reza clinic, Shiraz University of Medical Sciences, during March 2021 to June 2021. Patients will allocate to the each groups of corticosteroid or prolotherapy groups with block randomization. The operator physician and participants will be blinded to the group allocation.

Participants/Inclusion and exclusion criteria

The inclusion criteria for participants are diagnosis of plantar fasciitis, age older than 18 and not using of analgesics during the study. The exclusion criteria are diagnosis other disease which involves foot joints; including ankylosing spondylitis, Reiter's syndrome, rheumatoid arthritis and gout; a history of drug sensitivity to the drug compounds using in the study, a history of local injection for foot pain within the past 6 months, pregnancy and lactation.

Intervention groups

In corticosteroid group, 40 milligrams of methyl acetate an 1 cc of lidocaine 2% solution will inject with the plantar approach under ultrasound guide. In prolotherapy group, 1 cc of dextrose 50% solution and 1 cc lidocaine 2% solution will inject as above.

Main outcome variables

Patients' pain score in 1month and 3 month follow up; patients' foot function index in 1 month and 3 month

follow up.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210305050582N1**

Registration date: **2021-03-19, 1399/12/29**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-19, 1399/12/29**

Update count: **0**

Registration date

2021-03-19, 1399/12/29

Registrant information

Name

Fateme Alaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 25 3270 4132

Email address

ftm.alaei@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-10, 1399/12/20

Expected recruitment end date

2021-06-10, 1400/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of ultrasound guided prolotherapy and ultrasound guided corticosteroid injection on pain score and foot function in patients with plantar fasciitis.

Public title

Prolotherapy and corticosteroid injection in plantar fasciitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with plantar fasciitis. No analgesic using during the study. Over 18 years of age.

Exclusion criteria:

Patients with ankylosing spondylitis. Patients with Reiter's syndrome. Patients with rheumatoid arthritis. Patients with gout disease. Anatomical disturbance in the site of the lesion. Drug sensitivity to corticosteroids or lidocaine. Any local injection for plantar fasciitis within the past 6 months (including corticosteroid, platelet rich plasma, prolotherapy and lidocaine). Known coagulopathy. Pregnancy or lactation.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will allocate to the either corticosteroid or prolotherapy groups by block randomization. Block randomization will be done by random blocks of four with letters A and B, without replacement. For example, for AABB block, the first two patients will include group A and the latter two patients will include group B. Allocation of treatment to the groups A and B will be done by simple randomization, using a coin.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the present study, the participant, the physician; who who performs the procedure; and the study assistant; who is the responsible of patients' follow up; will be blinded to the groups allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Faculty of research, Floor 7th, Central Building of Shiraz University of Medical Sciences, Zand Ave.

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7134814336

Approval date

2019-09-16, 1398/06/25

Ethics committee reference number

IR.SUMS.MED.REC.1398.397

Health conditions studied**1****Description of health condition studied**

Plantar fasciitis

ICD-10 code

M70-M79

ICD-10 code description

Other soft tissue disorders

Primary outcomes**1****Description**

The patients' reported pain score based on visual analog scale (VAS).

Timepoint

Before the intervention, first month and third month.

Method of measurement

Patients will quantify their pain by VAS using the numbers 1; for the least severity; to 10; for the most severity; of he pain.

2**Description**

The foot function index (FFI)

Timepoint

Before the intervention, first month and third month.

Method of measurement

Standard FFI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Treatment with local injection of 40 mg methyl prednisolone acetate and 1 milliliter of 2% lidocaine solution under ultrasound guide with plantar approach. A 23 gauge needle will be used for injection.

Category

Treatment - Drugs

2

Description

Intervention group 2: Treatment with injection of 1 milliliter of 50% dextrose solution and 1 milliliter of 2% lidocaine solution under ultrasound guide with plantar approach. A 23 gauge needle will be used for injection.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza clinic, Shiraz University of Medical Sciences.

Full name of responsible person

Fateme Alaei

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Imam Reza clinic, Namazi Sq. Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fateme Alaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Aref Nasiri

Position

Assistant professor

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Specialist

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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

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

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

Title and more details about the data/document

Data can be published as SPSS file.

When the data will become available and for how long

Accessible after publishing the results

To whom data/document is available

Universities and relevant research centers.

Under which criteria data/document could be used

For using in metanalysis by academic research centers.

From where data/document is obtainable

The attending professor: Aref Nasiri, MD Phone number: 00989144068129

What processes are involved for a request to access data/document

Under the permission of the attending professor and the research faculty of Shiraz University of Medical Sciences.

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Fateme Alaei

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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