

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of autologous blood transfusion with methylprednisolone injection in the treatment of patients with plantar fasciitis

Protocol summary

Study aim

1. Determining and comparing the effect of methylprednisolone injection and autologous blood transfusion in the treatment of patients with plantar fasciitis by age
2. Determining and comparing the effect of methylprednisolone injection and autologous blood transfusion in the treatment of patients with plantar fasciitis by sex
3. Determining and comparing the effect of methylprednisolone injection and autologous blood transfusion in the treatment of patients with plantar fasciitis according to the presence of underlying disease
4. Determining and comparing the effect of methylprednisolone injection and autologous blood transfusion in the treatment of patients with plantar fasciitis according to the duration of the disease

Design

Interventional single blinded Simple randomized study, In two groups of 45 patients with plantar fasciitis during 2019 to 2021

Settings and conduct

Two groups of 45 patients with plantar fasciitis referred to the orthopedic clinic of Shahid Beheshti Hospital in Babol randomly receive methylprednisolone or autologous blood

Participants/Inclusion and exclusion criteria

inclusion criteria includes; Age over 18 years, heel pain for at least 4 weeks, pain intensity more than 5 based on visual analog scale index, tenderness at the junction of plantar fascia with calcaneus, ability to follow up for 6 months after starting treatment and informed written consent exclusion criteria includes; Heel surgery, evidence for calcaneus fracture, nerve damage, Achilles tendon injury, rheumatoid arthritis, local or systemic infection, peripheral vascular dysfunction, gout, coagulation disorder, pregnancy or lactation, corticosteroid injection in the last 3 months, non-steroidal anti-inflammatory drug uses In the last 7 days, history of allergy to injectable solutions

Intervention groups

Autologous blood group
Main outcome variables
Pain control

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160508027797N7**

Registration date: **2020-11-29, 1399/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-29, 1399/09/09**

Update count: **0**

Registration date

2020-11-29, 1399/09/09

Registrant information

Name

Masoud Bahrami Ferydoni

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 6285

Email address

m.bahrami@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of autologous blood transfusion with methylprednisolone injection in the treatment of patients with plantar fasciitis

Public title

The effect of autologous blood on plantar fasciitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years Heel pain for at least 4 weeks Pain intensity greater than 5 based on visual analog scale index Tenderness at the junction of plantar fascia with calcaneus Having the ability to follow up for 6 months after starting treatment Conscious written consent

Exclusion criteria:

Heel surgery Evidence in favor of calcaneus fracture Nerve damage Achilles tendon injury Rheumatoid Arthritis Local or systemic infection Peripheral vascular disorder Gout Coagulation disorder Pregnancy or breastfeeding Corticosteroid injection in the last 3 months Use of non-steroidal anti-inflammatory drugs in the last 7 days History of allergy to injectable solutions

Age

From 18 years old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: Envelopes and codes are prepared for randomization and simultaneous blinding for the patients. Each pack contains the type of injection (A: autologous blood; B: corticosteroids). Packs allocated by different codes. These codes are recorded for each patient. The order of the Pockets are determined by a statistician. After the patient enters the study, the pack is opened and the treatment for that patient is beginning.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the researcher and evaluator is unaware of the type of treatment and the statistician randomly determines the type of treatment of patients from a pre-prepared envelope

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Babol university of medical science

Street address

GanjAfrooz Street

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babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2020-04-07, 1399/01/19

Ethics committee reference number

IR.MUBABOL.REC.1399.038

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**

Pain control by autologous blood injection

Timepoint

First week, fourth week, third month, sixth month

Method of measurement

visual analogue scale index, role and maudsley scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 45 patients with plantar fasciitis who will receive 5 cc of autologous blood at the lesion site.

Category

Treatment - Drugs

2**Description**

Control group: 45 patients with plantar fasciitis who will receive 40 mg of methylprednisolone injection at the lesion site.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

shahid beheshti hospital of babol university of medical science

Full name of responsible person

Masoud Bahrami-Fereydouni

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

Babol University of Medical Sciences

Full name of responsible person

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Web page address

<http://research.mubabol.ac.ir/>

Grant name

Vice Chancellor for Research and Technology of Babol University of Medical Sciences

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

Yes

Title of funding source

Babol 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**

Babol University of Medical Sciences

Full name of responsible person

Masoud Bahrami-Fereydouni

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after Clearing individuals profile

When the data will become available and for how long

After the article is officially published

To whom data/document is available

For all researchers in this field

Under which criteria data/document could be used

For studies with the wider community, review studies and meta-analysis

From where data/document is obtainable

Email address

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

Confirmation of the person in charge of the study

Comments