Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Iran (Islamic Republic of)

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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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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
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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
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Position
Assistant Professor
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Person responsible for updating data

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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