

# 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

##### 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

**City**

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**

Reza Ghadimi

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research@mubabol.ac.ir

**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**

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 updating data

### Contact

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Babol University of Medical Sciences  
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Assistant Professor  
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**Other areas of specialty/work**  
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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