

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of ultrasound guided injection of botulinum toxin at the origin of plantar fasciitis with injection of botulinum toxin by Babcock method in the treatment of plantar fasciitis

#### Protocol summary

##### Study aim

The purpose of this study is to compare the effectiveness of botulinum toxin injection at the origin of the plantar fascia and the Babcock method in reducing pain, improving function, and reducing the thickness of the plantar fascia in patients with plantaris fasciitis.

##### Design

A single blind, randomized, phase 3 clinical trial on 60 patients. Random allocation software is used for randomization.

##### Settings and conduct

Outcome assessor, statistician and the researcher are all blind to treatment groups allocation; using pre-filled syringes and sealed envelopes. Subjects will be randomly allocated in 2 groups. The study will take place in Modarres hospital, Tehran.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: People aged 30 to 60 years who have been diagnosed with unilateral plantaris fasciitis and after 3 months from the onset of symptoms and the use of conservative treatments the patient's symptoms have not improved. Exclusion criteria: bilateral plantaris fasciitis, any ankle or foot deformity, neuropathic heel pain, uncontrolled diabetes, BMI more than 33, radicular low back pain, use of anticoagulants, pregnancy or breastfeeding, use of anticoagulant

##### Intervention groups

The first intervention group includes 30 patients who are treated with botulinum toxin injection (Masport, Masson Darou) at the origin of the plantar fascia along with one cc of lidocaine 2%. The second intervention group includes 30 patients who They are injected with 150 units of botulinum toxin by the Babcock method (90 units of which are at the junction of the plantar fascia with the calcaneus and 60 units in the arch of the foot and at a point between the front of the heel and the middle of the arch of the foot) and one cc of lidocaine.

##### Main outcome variables

Heel pain, pain pressure threshold, patient's performance in daily tasks, Assessment of plantar fascia thickness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130523013442N33**

Registration date: **2023-09-17, 1402/06/26**

Registration timing: **prospective**

Last update: **2023-09-17, 1402/06/26**

Update count: **0**

##### Registration date

2023-09-17, 1402/06/26

##### Registrant information

##### Name

Seyed Ahmad Raeissadat

##### Name of organization / entity

Modares Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2273 1112

##### Email address

a\_raeissadat@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2024-05-21, 1403/03/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of ultrasound guided injection of botulinum toxin at the origin of plantar fasciitis with injection of botulinum toxin by Babcock method in the treatment of plantar fasciitis

**Public title**

Comparison of ultrasound guided injection of botulinum toxin at the origin of plantar fasciitis with injection of botulinum toxin by Babcock method in the treatment of plantar fasciitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

People aged 30 to 60 years who have been diagnosed with unilateral plantaris fasciitis based on history and clinical examination. After 3 months from the onset of symptoms and the use of conservative treatments, including rest, anti-inflammatory drugs, physical modalities and exercise therapy, the patient's symptoms have not improved.

**Exclusion criteria:**

History of previous surgery for plantaris fasciitis. History of injection for treatment of plantaris fasciitis in the last 3 months. Bilateral plantaris fasciitis Presence of systemic inflammatory diseases such as rheumatoid arthritis and seronegative arthritis. History of vascular insufficiency and neuropathic heel pain Existence of concomitant diseases in the lower limbs, such as a history of tarsal tunnel syndrome symptoms and positive tinel sign. Presence of effusion in the ankle, which suggests an intra-articular disease Old fracture of calcaneal bone. Presence of retrocalcaneal bursitis, Achilles tendinopathy and ankle osteoarthritis Any ankle or foot deformity, including flat foot and pes cavus. Uncontrolled diabetes BMI more than 33 Radicular low back pain Presence of local infection or trauma near the injection site Use of anticoagulants Presence of diseases that involve the neuromuscular junction, such as myasthenia gravis and Eaton Lambert Known allergy and sensitivity to botulinum toxin or corticosteroids Presence of cyst or bone mass in the area of the heel Pregnancy or breastfeeding

**Age**

From **30 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this clinical trial study, 60 patients diagnosed with plantar fasciitis will be randomly enrolled. Block randomization method will be used for random allocation of people in the studied groups. In this method, blocks of 6 will be used with a ratio of 1:1. Random Allocation software will be used to generate random sequences. For concealment, random allocation concealment method will be used, which is marked with the letters A (group receiving botulinum toxin in the origin of plantar fasciitis) and B (group receiving botulinum toxin by Babcock method) and recorded on cards. These cards will be placed in the sealed envelopes in order. In order to maintain the created sequence, numbering will be done on the outer surface of the envelopes. Finally, the numbered envelopes will be placed in a folder. Then based on The order of entry of the eligible participants, the envelopes will be opened and the assigned group of that participant will be known.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The study is single blind because it is not possible to blind patients and the clinical caregiver responsible for drug injection due to the difference in botulinum toxin injection location in the two groups. The injections are performed by a physical medicine specialist. The researcher and the person conducting the follow up and data analysts and outcome assessors who are blinded and unaware of the intervention performed on each group of patients And only the final data in the form of the first and second groups and random numbers assigned to each patient will be available.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Research Ethics Committees of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti University of Medical sciences, Shahid Arabi Street, Yaman Street, Shahid Chamran Highway, Velenjak, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2023-06-11, 1402/03/21

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1402.170

## 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**

Evaluation of the patient's heel pain

**Timepoint**

At the beginning of the study (before intervention) and 6 weeks and 24 weeks after the intervention

**Method of measurement**

Visual analogue scale (VAS)

### 2

**Description**

Assessment of plantar fascia thickness

**Timepoint**

At the beginning of the study (before intervention) and 6 weeks and 24 weeks after the intervention

**Method of measurement**

Measuring the thickness of the plantar fascia with ultrasonography

### 3

**Description**

Pain pressure threshold

**Timepoint**

At the beginning of the study (before intervention) and 6 weeks and 24 weeks after the intervention

**Method of measurement**

Algometer

### 4

**Description**

Assessment of the patient's performance in daily tasks

**Timepoint**

At the beginning of the study (before intervention) and 6 weeks and 24 weeks after the intervention

**Method of measurement**

Using the FFI-R questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: included 30 patients who are treated with 150 unit botulinum toxin injection (Masport, Masson Darou) at the origin of the plantar fascia with 1 cc of 2% lidocaine.

**Category**

Treatment - Drugs

### 2

**Description**

Intervention group: Including 30 patients who are treated with 150 units botulinum toxin (Masport, Masson Darou) by Babcock method (90 units at the junction of the plantar fascia with the calcaneus and 60 units in the arch of the foot and at a point between the front of the heel and the middle of the foot's arch) with one cc of 2% lidocaine..

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Shahid Modarres Hospital

**Full name of responsible person**

Seyed Ahmad Raeissadat

**Street address**

Shahid Modarres hospital , Kaj Square, Sa'adat abad

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**Postal code**

1998734383

**Phone**

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**Email**

alin7093@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Ahmad Raeissadat

**Street address**

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**Email**

a\_raeissadat@sbm.ac.ir

**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**

Ali Nazari Noudoshan

**Position**

Resident of Physical medicine and Rehabilitation

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

Shahid Modarres Hospital, Kaj square, Saadat abad

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Ahmad Raeissadat

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident of Physical medicine and Rehabilitation

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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**City**

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**Province**

Tehran

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**Phone**

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**Email**

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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**

Undecided - It is not yet known if there will be 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**

All the data of people participating in this study can be shared after deidentifying people

**When the data will become available and for how long**

The access period starts one year after the results are published.

**To whom data/document is available**

Data of this study will be available to researchers working in academic and scientific institutions.

**Under which criteria data/document could be used**

If the goal of the researchers is to conduct a systematic review and meta-analysis on the data, the non-identifiable data of the patients will be provided to the researchers.

**From where data/document is obtainable**

By sending an email to [alin7093@gmail.com](mailto:alin7093@gmail.com)

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

The application should contain information about the applicant, his/her affiliation, phone number, e-mail and the reason for his/her request. If these items are presented and the information related to the applicant's plan is registered and confirmed in the PROSPERO system, the information will be provided to the applicant.

**Comments**