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
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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

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Sponsors / Funding sources

1

Sponsor

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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
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 Nodoushan

Position
Resident of Physical medicine and Rehabilitation

Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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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
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

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