Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effectiveness of Botulinium toxin A administration to Gastrecnemius muscle on pain and function among patients with chronic plantar fascitiis, Randomized control double blinded study

Protocol summary

Study aim

The objective of the present study is to investigate the effect of botulinum toxin type A injection into the gastrocnemius muscle on pain reduction and functional improvement in patients with chronic plantar fasciitis."

Design

This double-blind controlled study uses block randomization. Forty-two participants, based on statistical calculation, will be randomly assigned into two groups (21 per group) using simple randomization within six blocks of seven individuals.

Settings and conduct

Syringes in both groups will appear identical, with only the contents differing. A third party will prepare and deliver syringes based on block randomization and will be the only one aware of their contents. Both the researcher and participants will remain blinded until final data analysis, which will be conducted by the researcher.

Participants/Inclusion and exclusion criteria

Patients will be selected from individuals with a clinical diagnosis of chronic plantar fasciitis who have not responded to at least two months of conservative treatment and have referred to a private orthopedic clinic. The sample size is calculated to be 42 participants based on statistical formulas. After obtaining informed consent, participants will be randomly allocated (using simple randomization) into two groups of 21: an intervention group and a control group."

Intervention groups

In the intervention group, 70 units of botulinum toxin A will be injected into the upper third of the medial gastrocnemius, followed by an 8-week stretching program. The control group will receive an equal volume of normal saline and the same exercise regimen.

Main outcome variables

(VAS)Visual Analogue Scale for pain and Foot and Ankle Ability measure (FAAM) questionnaire

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250220064788N1**
Registration date: **2025-05-29, 1404/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2025-05-29, 1404/03/08**
Update count: **0**

Registration date

2025-05-29, 1404/03/08

Registrant information

Name

Delara Salehifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-10-06, 1404/07/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effectiveness of Botulinium toxin A administration to Gastrecnemius muscle on pain and function among patients with chronic plantar fascitiis, Randomized control double blinded study

Public title
Effectiveness of Botox injection on chronic Plantar fasciitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
People with a clinical diagnosis of chronic plantar fasciitis who have received supportive treatment for at least 2 months and have not responded to the treatment Presence of pain in the heel for at least two months with a VAS between numbers 3 and 7 (out of 10) at the time of examination

Exclusion criteria:
Suffering from a significant physical and mental illness that increases the risk of disrupting the study process Drug or Substance addiction Pregnancy or breastfeeding The presence of injury in the studied lower limb A history of Corticosteroid or PRP injection in the plantar fascia during at least the last 6 months History of Neuromuscular diseases such as Myasthenia gravis Allergy to botulinum toxin or eggs Suffering from orthopedic and medical problems that are contrary to the possibility of the person's participation in the study Heel pain with diagnoses other than plantar fasciitis The use of foot Orthoses since the time of entering the study Use of NSAID with anti-inflammatory dose during the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, Block randomization is used. 42 participants in this research will be placed in six blocks of seven randomly. Allocation of each participant to intervention and control groups based on randomization was done by a person other than the researcher (a third party) and a syringe with unknown content for the researcher and volunteer was given to the researcher for injection by a third party. The information related to the contents of the syringes used by each volunteer will remain in the possession of a third party until the final analysis of the information, and the researcher and the volunteers will not be aware of this information.

Blinding (investigator's opinion)
Double blinded

Blinding description
The appearance of the syringes of the intervention and control groups is completely the same and only the contents of the syringes are different from each other. The preparation and delivery of the syringes to the researcher before each stage of the study will be done by a third party based on randomization blocks. Only the third party will be aware of the contents of the delivered syringes (neither the researcher nor the volunteers will be informed) and the researcher will not be aware of the content of the injected syringes for each volunteer until the final analysis of the data. The final analysis of the data will be done by the researcher.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of SINA Hospital- Tehran University of Medical Sciences

Street address
Imam khomeini avenue

City
Tehran

Province
Tehran

Postal code
1136746911

Approval date
2024-05-02, 1403/02/13

Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1403.014

Health conditions studied

1

Description of health condition studied
Plantar fascial fibromatosis

ICD-10 code
M72.2

ICD-10 code description
Plantar fascial fibromatosis

Primary outcomes

1

Description
Tenderness using VAS (Visual Analog Scale)

Timepoint

Before injection and after eight weeks

Method of measurement

A 10-mm line will be drawn on paper, marked with '0' at one end and '10' at the other. Participants will be asked to indicate their overall pain level by marking a point on the line.

2

Description

FAAM questionnaire

Timepoint

Before injection and after eight weeks

Method of measurement

Responses to the questionnaire and the total scores of the daily activities and sports subscales will be recorded.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:In the intervention group, 70 units of Botulinum Toxin A are injected into the upper third of the medial head of the gastrocnemius muscle. The drug, produced by the 500-unit Masport company, is diluted with 2.5 cc of normal saline for injection. Subsequently, a stretching exercise program for the lower limb is prescribed for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group:In the control group, the same volume of normal saline is injected, and a similar 8-week exercise program is prescribed as in the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Private orthopedic clinic

Full name of responsible person

Arvin Najafi

Street address

Hafte Tir Blvd

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Karaj

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Tehran

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3135655404

Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Remind kordi

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Keshavarz Blvd

City

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Province

Tehran

Postal code

1417653761

Phone

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Declaration salehifar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Sport Medicine

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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Margam Abolhasani
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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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
No - There is not 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
The present research has been registered as a proposal for the thesis of the Sports Medicine Residency Program. The resulting thesis from this proposal, including all participant data, study protocol, statistical analyses, and the full study report encompassing all variables, will be submitted to Tehran University of Medical Sciences and the Department of Sports Medicine. It is noteworthy that, upon approval of the thesis, an article containing all the mentioned elements will be published in a journal relevant to the topic of the research. Please note that access to raw data not included in the final report or published article requires direct communication with the principal investigator of the study
When the data will become available and for how long
A period of two years has been estimated for all stages of the study until its submission as a thesis. The data obtained from this research will be submitted for publication as an article after the thesis has been approved at the end of the two-year period. Access to the raw data not included in the final report or the published article will be possible after the article's publication through direct communication with the principal investigator of the study.
To whom data/document is available
The data obtained from this research will be available to all interested individuals, and there will be no restrictions on access.
Under which criteria data/document could be used
There are no restrictions on the use, publication, or further processing of the data from this study, provided that prior communication is established with the principal investigator via email or other means, and the necessary permission is granted by the principal investigator.
From where data/document is obtainable
To access the information of this study, the interested individual may contact the principal investigator via email or phone.
What processes are involved for a request to access data/document
The permission to use the information will be granted to the interested individual as soon as the email is received or the phone contact is made, and the requested information will be promptly sent to the individual via email.

Comments