

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effectiveness of Botulinum toxin A administration to Gastrocnemius muscle on pain and function among patients with chronic plantar fasciitis, 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)

##### Phone

+98 21 6119 2282

##### Email address

d-salehifar@razi.tums.ac.ir

##### 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 Botulinum toxin A administration to Gastrocnemius muscle on pain and function among patients with chronic plantar fasciitis, 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

##### **City**

Karaj

##### **Province**

Tehran

##### **Postal code**

3135655404

#### **Phone**

+98 905 260 5759

#### **Email**

delaraa.salehifar@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Remind kordi

##### **Street address**

Keshavarz Blvd

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417653761

##### **Phone**

+98 21 8163 3698

##### **Email**

vcr@tums.ac.ir

#### **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

##### **Street address**

Imam khomeini Ave

##### **City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Email**

Delaraa.salehifar@gmail.com

**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**

Sport Medicine

**Street address**

Imam khomeini Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Email**

dr\_m\_abolhasani@yahoo.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Delara Salehifar

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Sport Medicine

**Street address**

Imam khomeini Ave

**City**

Tehran

**Province**

Tehran

**Postal code**

1136746911

**Phone**

+98 21 6634 8500

**Email**

Delaraa.salehifar@gmail.com

**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