

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Clinical trial comparison of ultrasound guided local injection of botulinum toxin type A with corticosteroid in treatment of chronic plantar fasciitis

Protocol summary

Study aim

To compare the clinical effectiveness of local botulinum toxin injection with corticosteroid injection for plantar fasciitis

Design

A total number of 40 patients will randomly be categorized into one of the following group, group A: will receive ultrasound guided localized injection of 150 units botulinum toxin in the intrinsic foot muscles. Group B: will receive ultrasound guided localized injection of 1 cc triamcinolone and 1 cc lidocaine in the plantar fascia.

Settings and conduct

This randomized control trial will be conducted in Firoozgar hospital, Tehran, Iran. This hospital is affiliated to the Iran university of medical sciences. Patients are randomly divided into two groups in closed packing.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18 to 75; A typical history of plantar fasciitis and localized tenderness in the medial side of the heel; Exclusion criteria: Evidence of calcaneal fracture; history of heel surgery; inflammatory diseases; diabetes mellitus; local or systemic infections; gout; blood coagulation disorders

Intervention groups

Overall, 40 patients will randomly be allocated equally into two groups

Main outcome variables

Pain intensity at the standing position; early morning pain; pain on joint movement, daily activities, climbing stairs and exercise tolerance. The outcomes are evaluated repeatedly up to 3 months after interventions.

General information

Reason for update

Edit sampling date

Acronym

PF

IRCT registration information

IRCT registration number: **IRCT20190428043404N1**

Registration date: **2019-12-25, 1398/10/04**

Registration timing: **prospective**

Last update: **2020-08-24, 1399/06/03**

Update count: **1**

Registration date

2019-12-25, 1398/10/04

Registrant information

Name

Golam Reza Raissi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-01, 1398/10/11

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparison of ultrasound guided local injection of botulinum toxin type A with corticosteroid in treatment of chronic plantar fasciitis

Public title

Comparison of corticosteroid with botulinum toxin in treatment of chronic calcaneal spur

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 history of plantar fasciitis, patients suffering from heel pain with a VAS more than 4 months for at least two months whose history physical exam and sonography confirmed plantar fasciitis
Exclusion criteria:
 History of direct trauma other causes of heel pain (fracture, tumor, infection, nerve entrapment) systemic inflammatory or soft tissue disease disk herniation with S1 radiculopathy poor controlled diabetes history of gout association with other causes of foot pain (severe osteoarthritis, Morton neuroma, metatarsalgia) surgery or injection in fascia since 6 months ago coagulopathy pregnancy hypersensitivity to corticosteroid or botulinum toxin or lidocaine antibody against botulinum toxin any treatment for the condition since 4 weeks ago anti-inflammatory drugs, physiotherapy, splint, iontophoresis, phonophoresis and shock wave in the last 3 months

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Investigator
- Data analyst

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
simple randomization

Blinding (investigator's opinion)
Double blinded

Blinding description
patients are randomly divided into 2 groups in closed packing

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Iran University of Medical Sciences (IUMS)
Street address
 Iran university of Medical Sciences, Hemmat highway, Tehran, Iran
City
 Tehran
Province
 Tehran
Postal code
 1449614535
Approval date
 2018-12-04, 1397/09/13
Ethics committee reference number
 IR.IUMS.FMD.REC.1397.091

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

pain intensity at the standing position

Timepoint

All the outcomes were evaluated at the baseline visit, 1 month and 3 months after the intervention.

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Early morning pain, pain on joint movement, daily activities, climbing stairs and exercise tolerance

Timepoint

All the outcomes were evaluated at the baseline visit, 1 month and 3 months after the intervention

Method of measurement

Visual analog scale. we also assess the ability to perform daily activities, climbing stairs and exercise tolerance with FAAM questionnaire

Intervention groups

1

Description

Intervention group: will receive ultrasound guided localized injection of 150 unit botulinum toxin type A in

the foot intrinsic muscles.

Category

Treatment - Drugs

2**Description**

Control group:will receive ultrasound guided localized injection of 1 cc methylprednisolone and 1 cc normal saline 0.9% in the attachment of the plantar fascia to the calcaneal bone

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Firoozgar Hospital

Full name of responsible person

Dr.Gholamreza Raissi

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Sasan Sadeghi Nik

Position

Resident of physical medicine and rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Gholamreza Raissi

Position

Associate professor of Physical Medicine and Rehabilitation

Latest degree

Specialist

Other areas of specialty/work

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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

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

The study will be published in an article

When the data will become available and for how long

Just after publication

To whom data/document is available

researchers

Under which criteria data/document could be used

for research purpose

From where data/document is obtainable

from the indexing journal website

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

the researcher must download the article

Comments