# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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 fascitis 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)

**Phone**
+98 21 8214 1612

**Email address**
raissi.gh@iums.ac.ir

**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 leate two month whose history physical exam and sonography confirmed plantar fasciitis

**Exclusion criteria:**

History of direct trauma other causes of heel pain( fracture,tumor,infection,nerve entrapement) 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,matatarsalgia) surgery or injection in fascia since 6 month ago coagulopathy pregnancy hypersensitivity to corticosteriod or botulinum toxin or lidocain 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 month

**Age**

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

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator
- Data analyser

**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

**Street address**

Firoozgar Hospital,Beh Afarin St,Valiasr SQ;Tehran;Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1593748711

**Phone**

+98 21 8893 7902

**Fax**

+98 21 8894 2622

**Email**

H_Firoozgar@yahoo.com

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Seyyed Abbas Motavalian

**Street address**

Iran university of medical sciences,Hemmat highway; Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 8670 4704

**Fax**

+98 21 8862 2707

**Email**

amotevalian@iums.ac.ir

**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

**Street address**

Firoozgar hospital;Beh Afarin St;Vali asr SQ;Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1593748711

**Phone**

+98 21 8214 1229

**Fax**

+98 21 8894 2622

**Email**

sasansadeghinik444@gmail.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Gholamreza Raissi

**Position**

Associate professor of Physical Medicine and Rehabilitation

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

**Street address**

Firoozgar Hospital;Beh Afarin St;Valiasr SQ;Tehran;Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1593748711

**Phone**

+98 21 8893 7902

**Fax**

+98 21 8894 2622

**Email**

graissi@gmail.com

## Person responsible for updating data

**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

**Street address**

Firoozgar hospital;Beh Afarin St;Valiasr SQ;Tehran;Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1593748711

**Phone**

+98 21 8893 7902

**Email**

Sasansadeghinik444@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**

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**