Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Short-Term Effect of Ultrasonography -Guided Botulinum Toxin A Injection in the Treatment of Foot and Ankle Disorders: A Multi-center Randomized, Triple-Blinded Study

Protocol summary

Study aim

Evaluation of short-term effects of Botox in improving the symptoms of patients with Achilles tendinopathy

Design

We intend to investigate for the first time the effects of Botox on the improvement of symptoms by conducting a randomized, multi-center, triple-blinded, placebo-controlled clinical trial (Phase III) with three months of follow-up. Patients with Achilles tendinopathy, metatarsalgia, or plantar fasciitis. The number of participants in each group is 30 randomly selected using randomization software. The exact injection site is determined by an ultrasound-guided radiologist.

Settings and conduct

Patients will be selected from three medical centers (Akhtar, Rasoul, and Tajrish Hospital). All participants will confirm the informed consent form as well as the description of the treating physician. The patients, the doctors, and the statistical analyst of this project will not know the identity of the patients in each group (triple blindness).

Participants/Inclusion and exclusion criteria

Clinically confirmed chronic Achilles tendinopathy, metatarsalgia, or flat foot are included. Exclusion criteria include age< 18 years osteoarticular pathology of the ankle fibromyalgia radiculopathy or disc herniation history systemic inflammatory diseases peripheral neuropathic diseases and any contraindications to intramuscular BoNT-A injection.

Intervention groups

Subcutaneous injection of Botox at a dose of 70 IU of botulinum solution type A (diluted in 10 ml of normal saline) in the one-third proximal area of the medial head of the gastrocnemius for the intervention group and a similar volume of normal saline (1.5 liters) in the control group.

Main outcome variables

Patient pain, patient function, calf power, and ankle dorsiflexion, quality of life, and injection satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047525N2**
Registration date: **2021-05-16, 1400/02/26**
Registration timing: **prospective**

Last update: **2021-05-16, 1400/02/26**
Update count: **0**

Registration date

2021-05-16, 1400/02/26

Registrant information

Name

Mohammad Movahedinia

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-06, 1400/06/15

Expected recruitment end date

2023-03-06, 1401/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Short-Term Effect of Ultrasonography -Guided Botulinum Toxin A Injection in the Treatment of Foot and Ankle Disorders: A Multi-center Randomized, Triple-Blinded Study

Public title

Botulinum Toxin A Rolls in Foot and Ankle Muscular Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Clinically confirmed chronic achilles tendinopathy, metatarsalgia, or flat foot Proved chrionicity, described as: persistent pain (>6 months), despite medicaltreatment consisting of rest, analgesics, anti-inflammatories, localcorticosteroid injections, and/or physiotherapy.

Exclusion criteria:

age< 18 years osteoarticular pathology of the ankle fibromyalgia any conflict of interest associated with the patient'spain, including an unresolved workplace injury or ongoing legal proceedings for compensation; or postoperative symptoms. radiculopathy or disc herniation history systemic inflammatory diseases peripheral neuropathic diseases e.g diabetes contraindications to intramuscular BoNT-A injection, including suspected pregnancy, breastfeeding, a history of neuromuscular pathology, or current anticoagulant or aminoglycoside treatment. Patients who hadreceived BoNT-A injections previously were excluded to avoidtreatment ineffectiveness due to immunization against BoNT-A.

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use restricted randomization to allocate equal patients in each group. We will do permuted block randomization to have 3 blocks of 60 patients (30 patients in intervention and 30 in the control group). Each block is for one of the 3 diseases of this study. we will first stratified randomization according to the center and use Random allocation software for randomization. For allocation concealment, we will use central randomization in Akhtar hospital (Tehran) and gather the data from the other two centers (Tajrish and Rasoul). We classify the samples according to the classification center, and then we generate a random sequence in each class with the help of randomization software. To hide random allocation, we use the central randomization method. Random sequencing is performed at Akhtar Hospital Center in Tehran and sampling is performed simultaneously at Tajrish and Rasoul Hospital centers in Tehran at the same time. The secretary in charge of the Akhtar Center, based on the order in which the participants entered the study, communicated with the secretary of the other center and asked about the random assignment of the participant to a special group. In the randomization process, the person who creates the random sequence, and the person who examines the participants in terms of inclusion and exit criteria is a secretary at Akhtar Hospital, which is responsible for maintaining information and confidentiality until the end of the study.

Blinding (investigator's opinion)

Triple blinded

Blinding description

We will use a triple-blinded study with blinding of participants, principle investigators, healthcare providers (Physicians, nurses, physiotherapists, etc.) who care for participants during the trial, outcome assessors (analyzer), and manuscript writer. The corresponding secretary in Akhtar, who will allocate randomization, and the other two center secretaries, who should report the randomization process will be alert about patients' specific group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences Ethics Committee

Street address

Shahid Beheshti University of Medical Sciences, Next to Ayatollah Taleghani Hospital, Evin, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1005

Health conditions studied

1

Description of health condition studied

Flat feet (also called pes planus or fallen arches) is a postural deformity in which the arches of the foot collapse, with the entire sole of the foot coming into complete or near-complete contact with the ground.

ICD-10 code

M21.4

ICD-10 code description

Flat foot [pes planus] (acquired)

2

Description of health condition studied

Metatarsalgia, literally metatarsal pain and colloquially known as a stone bruise, is a general term used to refer to any painful foot condition affecting the metatarsal region of the foot. This is a common problem that can affect the joints and bones of the metatarsals.

ICD-10 code

M77.4

ICD-10 code description

Metatarsalgia

3

Description of health condition studied

Achilles tendinitis (also Achilles tenosynovitis or Achilles tendinopathy) is tendinitis of the Achilles tendon, generally caused by overuse of the affected limb and is more common among athletes training under less than ideal conditions.

ICD-10 code

M76.6

ICD-10 code description

Achilles tendinitis

Primary outcomes

1

Description

VAS score: The visual analog scale (VAS) is a validated, subjective measure for acute and chronic pain. Scores are recorded by making a handwritten mark on a 10-cm line that represents a continuum between “no pain” and “worst pain.”

Timepoint

Comparison of visual analog scale (VAS) between intervention and placebo groups in two time periods before injection and 3 months after injection

Method of measurement

The visual analog scale (VAS)

2

Description

Function assessment by American Orthopaedic Foot and Ankle Society (AOFAS) questionnaire range from 0 to 100, with healthy ankles receiving 100 points.

Timepoint

Comparison of visual analoge scale (VAS) between intervention and placebo groups in two time periods before injection and 3 months after injection

Method of measurement

AOFAS questionnaire

3

Description

Ankle dorsiflexion measured as degree in physical exam

Timepoint

Comparison of visual analoge scale (VAS) between intervention and placebo groups in two time periods before injection and 3 months after injection

Method of measurement

physical exam

4

Description

Calf power as standing time on one toe (seconds)

Timepoint

Comparison of visual analoge scale (VAS) between intervention and placebo groups in two time periods before injection and 3 months after injection

Method of measurement

physical exam

Secondary outcomes

1

Description

Quality of life 0-100 (No interference - complete interference with life)

Timepoint

Comparison of VAS score between intervention and placebo groups in two time periods before injection and 3 months after injection

Method of measurement

Asking the patient

2

Description

Patient satisfaction with the injection (Absolutely - to some extent - not at all)

Timepoint

Comparison of VAS score between intervention and placebo groups in two time periods before injection and 3 months after injection

Method of measurement

Asking the patient

3

Description
Symptom improvement rate based on Likert (worsening-unchanged-slightly better-completely better)
Timepoint
Comparison of VAS score between intervention and placebo groups in two time periods before injection and 3 months after injection
Method of measurement
Asking the patient

4

Description
Tendency to inject the same in yourself or loved ones (strongly agree - somewhat agree - not at all)
Timepoint
Comparison of VAS score between intervention and placebo groups in two time periods before injection and 3 months after injection
Method of measurement
Asking the patient

Intervention groups

1

Description
Intervention group: In this group, patients receive Botox injection of 70IU solution of botulinum type A (diluted in 10 ml of normal saline).
Category
Treatment - Drugs

2

Description
Control group: In this group, a similar volume of normal saline (1.5 liters) will be injected.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar hospital
Full name of responsible person
Mohammad Movahedinia
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Unit1, Floor1, No16, Alley Yousef, St Mirkhani, Sq Tohid
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2

Recruitment center
Name of recruitment center
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3

Recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
Mohammad Movahedinia
Position
Orthopaedic resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
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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

There is a plan to make clinical study reports and data of this study available to other researchers (typically after the end of the study). These data consist of all variables (except patient identification) for half of each group of participants (control/intervention) provided in SPSS format.

When the data will become available and for how long

En The start date of data availability will be in March 2023.

To whom data/document is available

Documents will be shared and available for researchers working in any academic institution.

Under which criteria data/document could be used

Any requests to access all documents (for example for a systematic review) should be sent to the responsible researcher.

From where data/document is obtainable

To contact the corresponding researcher: Email: mmvn93@gmail.com WhatsApp: 00989216361088 Linkedin: mohammad movahedinia

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

After contacting the corresponding researcher, documents will be sent in one month

Comments