

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of ultrasound guided intramuscular injection of botulinum toxin (type A) in the distal of the vastus lateralis muscle on pain relief and performance improvement in patients with patellofemoral pain syndrome: A randomized clinical trial

Protocol summary

Study aim

Determining the effect of intramuscular botulinum toxin A injection under ultrasound in the distal vastus lateralis muscle on reducing pain and improving performance in patients with patellofemoral pain syndrome.

Design

Two arm double blinded parallel group randomised trial, phase III trial, with a minimum of 52 patients

Settings and conduct

The participants are divided into two groups. During the treatment period and one week before the start of the physiotherapy program, patients will not be allowed to use non-steroidal anti-inflammatory drugs and pain relievers. After the screening, the included patients will be subjected to initial evaluations. In all patients, AP, lateral and axial view radiography of the knee will be done to check the grade of arthritis and joint space. All measurements will be done before starting the treatment and 2 months later.

Participants/Inclusion and exclusion criteria

Aged 18 to 45 years old; clinical diagnosis of PFP syndrome for more than 3 months; pain rating (out of 10) 4 or more; failure to respond to treatment despite receiving at least 8 weeks of non-invasive treatment including exercise therapy, exercise therapy and physical therapy.

Intervention groups

Patients of the intervention group will be treated with an ultrasound guided intramuscular injection of botulinum neurotoxin type A to induce temporary weakening of the distal vastus lateralis muscle in addition to the standard physiotherapy exercise program to strengthen and improve hip and knee joint muscle control for 8 weeks. The patients of the control group will undergo a placebo injection (normal saline) in the same place as the patients of the intervention group, as well as a standard

exercise program.

Main outcome variables

Knee pain level; Knee function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221202056684N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **retrospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Mohammadreza mashhadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-05, 1401/10/15

Expected recruitment end date

2023-01-12, 1401/10/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ultrasound guided intramuscular injection of botulinum toxin (type A) in the distal of the vastus lateralis muscle on pain relief and performance improvement in patients with patellofemoral pain syndrome: A randomized clinical trial

Public title

Effect botulinum toxin (type A) in patellofemoral pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18 to 45 years Clinical diagnosis of PFP syndrome for more than 3 months Pain rating (out of 10) 4 or more Failure to respond to treatment despite receiving at least 8 weeks of non-invasive treatment including exercise therapy, exercise therapy and physical therapy

Exclusion criteria:

Presence of knee joint effusion Presence of any evidence in favor of other tibiofemoral pathologies (patellar tendinopathy, presence of evidence of tibiofemoral osteoarthritis or patellofemoral joint space narrowing or arthrosis on radiographs (Kellgren-Lawrence grade II or higher), meniscal tear, knee instability) Evidence in favor of spinal canal stenosis, lumbar radiculopathy, neuropathy and lower limb neuronal damage Any intra-articular injection of the knee in the last 6 months (including hyaluronic acid, ozone or steroids) Body mass index > 35 Previous knee surgery Evidence of injury or inflammatory arthritis of the hip joint Allergy to BoNT-A Pregnancy

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

After signing the consent form to participate in this research, patients will be divided into two groups: A: BoNT-A injection and exercise therapy, and B: Placebo (normal saline) injection and exercise therapy.

Blinding (investigator's opinion)

Double blinded

Blinding description

The present study will be double-blind, so that the patient and the person who compares and records the results of the two groups will be unaware of the type of intervention. To keep them blind, the patients are placed in a lying position and their knees are protected with a cloth, and they will not actually see the injection.

Placebo

Used

Assignment

Parallel

Other design features

In addition to the original intervention, all of the included patients in both groups will be subjected to exercise therapy in the form of stretching of the gastrosoleus muscles, hamstrings, strengthening of the quadriceps muscles and hip adductor muscles for 8 weeks.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committee of the Faculty of Medicine, Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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19839-63113

Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.SBMU.MSP.REC.1400. 770

Health conditions studied**1****Description of health condition studied**

Patellofemoral pain syndrome

ICD-10 code

M22.2X9

ICD-10 code description

Patellofemoral disorders, unspecified knee

Primary outcomes**1****Description**

The amount of pain assessed by Visual Analogue Scale score

Timepoint

The beginning of the study and 2 months after the injection

Method of measurement

Visual Analogue Scale

2

Description

Examination of knee function using the Anterior Knee Pain Scale

Timepoint

The beginning of the study and 2 months after the injection

Method of measurement

Anterior Knee Pain Scale

3

Description

Examination of knee function using the Knee injury and Osteoarthritis Outcome Score-Patellofemoral subscale

Timepoint

The beginning of the study and 2 months after the injection

Method of measurement

Knee injury and Osteoarthritis Outcome Score-Patellofemoral subscale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: each knee will be receiving a total of one vial of 100 units of Botox Allergan (100U/vial) diluted to 10U in 0.1 ml (10 ml in total) in 5 divided doses by injection with ultrasound guidance, in the distal third of the VL muscle. The injections will start from a distance of 3 cm from the upper side of the patella bone and will be injected along a line towards the proximal side of the muscle. The distance between each injection and the next injection will be 2 cm. All injection cases will be given at a fixed time and for all participants in the same period of time, with full compliance with sterile conditions. In addition, each patient in both groups is subjected to exercise therapy in the form of stretching gastrosoleus muscles, hamstrings, strengthening the quadriceps muscles and hip adductor muscles for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: each of the knees will receive a total of 10

ml of normal saline in 5 divided doses by injection with ultrasound guidance, in the distal third of the VL muscle, starting at a distance of 3 cm from the upper side of the patella and along a line will be injected into the proximal side of the muscle. The distance between each injection and the next injection will be 2 cm. All injection cases will be done in a fixed time and for all participants in the same period of time, with full observance of sterile conditions. In addition, each patient in both groups is subjected to exercise therapy in the form of stretching gastrosoleus muscles, hamstrings, strengthening the quadriceps muscles and hip adductor muscles for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e-Tajrish hospital

Full name of responsible person

Mohammadreza Mashhadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Afshin Zarghi

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5th floor, Building No. 2, SBUMS, Arabi Ave,
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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**

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Full name of responsible person

Mohammadreza Mashhadi

Position

Resident

Latest degree

Medical doctor

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 collected data, including the background data, and the results investigated in this current study will be published in the form of an Excel file along with the publication of the results and the study protocol in a reputable research journal.

When the data will become available and for how long

The data of the study will be accessible from the time of publication of the study by sending an email to the corresponding author of the study

To whom data/document is available

The data of the study will be accessible for the use of researchers by sending an email to the corresponding author of the study

Under which criteria data/document could be used

The use of non-identifiable data of individuals is acceptable for conducting systematic review and meta-analysis studies

From where data/document is obtainable

In order to receive the data of this study, by sending an email to the corresponding author of this study, if the conditions required to access the information are met, the data will be provided to the requester.

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

The application should contain information about the applicant, his/her affiliation, phone number, e-mail and the reason for his/her request. If these items are presented and the information related to the applicant's plan is registered and confirmed in the PROSPERO system, the information will be provided to the applicant.

Comments