

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of trigger point dry needling of Quadratus lumborum on improvement of maximal isometric force of gluteus medius , pain and function of patellofemoral joint in patients with patellofemoral pain syndrome (single-blind randomized controlled trial)

#### Protocol summary

##### Study aim

The effect of dry needling of quadratus lumborum muscle technique on improvement of maximal isometric force of gluteus medius muscle, pain and patellofemoral joint function in patients with patellofemoral pain syndrome

##### Design

A randomized control trial with blinded examiner .52 patients , enrolled between February 2020 and June 2020.

##### Settings and conduct

This study done at Mahdiah Clinic and the participants randomly divided into two groups after filling out the consent form. Subjects in the intervention group receive 6 sessions of routine physiotherapy and 3 sessions of dry needle technique and in the control group receive only 6 sessions of routine physiotherapy. An evaluator who is blind to the grouping of patients and the treatment provided for each measure outcomes before the first session, immediately after the first session, and at the end of the sixth session.

##### Participants/Inclusion and exclusion criteria

Entry requirements: individuals between 18 and 40 years old; unilateral symptoms; gradual onset of pain not due to trauma and lasts for at least three months; anterior or knee pain that is aggravated by at least two of the following: \_ Prolonged sitting \_ Climbing stairs \_ Squat \_ Run \_ to jump \_ Lee Lee Exclusion criteria: a patella apprehension test or patella dislocation; knee effusion; radicular pain from hip or lumbar; surgery on the patellofemoral joint; signs of meniscus, collateral or cruciate ligament injury.

##### Intervention groups

The intervention group received 6 sessions of routine physiotherapy electrical stimulation and exercise therapy. In the first, third and fifth session, dry needle technique of the quadratus lumborum is performed.

Control group will receive 6 sessions of routine physiotherapy including electrical stimulation and exercise therapy.

##### Main outcome variables

Maximal isometric force of gluteus medius; pain; function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200113046113N1**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **prospective**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

##### Registration date

2020-02-01, 1398/11/12

##### Registrant information

##### Name

Fatemeh Mehrabi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3625 6142

##### Email address

fatemehhh@rehab.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-02-20, 1398/12/01

**Expected recruitment end date**

2020-06-19, 1399/03/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of trigger point dry needling of Quadratus lumborum on improvement of maximal isometric force of gluteus medius , pain and function of patellofemoral joint in patients with patellofemoral pain syndrome (single-blind randomized controlled trial)

**Public title**

The effect of Quadratus lumbarum muscle dry needling in patients with patellofemoral pain syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Men and women Aged 18-40 years Unilateral Insidious onset of symptoms not due to trauma present for at least 3 months Anterior or Peripatellar knee pain during at least 2 of the following:Prolonged sitting,Stair ascent, squatting, running, jumping, hopscotch Ability to read and write The minimum visual scale being 2

**Exclusion criteria:**

Positive patellar apprehension sign and History of recurrent patellar dislocation Knee joint effusion Hip or lumbar referred pain Previous surgery to the patellofemoral joint Prolonged nonsteroidal anti-inflammatory drug or corticosteroid use Known articular cartilage damage based on XRay Local or systemic infections or inflammation Bleeding disorders Taking anti coagulation medication Needle phobia Pregnancy The history of regular exercise activity Leg length discrepancy Hip adductor shortness Neurological low back pain Meniscal, Cruciate or collateral ligament injury

**Age**

From **18 years** old to **40 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Outcome assessor

**Sample size**

Target sample size: **52**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Subjects were randomly divided into control and experimental groups using randomized block design

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The evaluator is not aware of what patients are in the group and what treatment is being given to them.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Isfahan University of medical sciences

**Street address**

Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2020-01-02, 1398/10/12

**Ethics committee reference number**

IR.MUI.RESEARCH.REC.1398.570

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

Patellofemoral pain syndrome

**ICD-10 code**

M22.2X

**ICD-10 code description**

Patellofemoral disorders

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

Maximal isometric force of gluteus medius muscle

**Timepoint**

Before the first session, immediately after the first session, the end of the sixth session

**Method of measurement**

Handheld dynamometer

**2****Description**

Pain

**Timepoint**

Before the first session, immediately after the first session, the end of the sixth session

**Method of measurement**

### 3

#### **Description**

Function of patellofemoral joint

#### **Timepoint**

Before the first session, immediately after the first session, the end of the sixth session

#### **Method of measurement**

Kujala scoring questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: Six sessions routine physiotherapy include electrical stimulation performed by TENS and exercise therapy for knee joint . we also do Quadratus lumbarum muscle dry needling technique in first, third and fifth session.

#### **Category**

Rehabilitation

#### 2

#### **Description**

Control group: Six sessions routine physiotherapy include electrical stimulation performed by TENS and exercise therapy for knee joint

#### **Category**

Rehabilitation

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Mahdieh clinic

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

Fatemeh Mehrabi

##### **Street address**

Robot aval street

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8138913531

##### **Phone**

+98 31 3442 9946

##### **Email**

info@mahdiehisfahan.com

##### **Web page address**

<https://www.madiehisfahan.com>

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

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

Esfahan University of Medical Sciences

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

Shaghayegh Haghjoo Javanmard

##### **Street address**

Hezar Jerib street

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

8174673461

##### **Phone**

+98 31 3668 5149

##### **Email**

research@mui.ac.ir

##### **Web page address**

<https://www.research.mui.ac.ir>

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

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

Fatemeh Mehrabi

##### **Position**

Master student

##### **Latest degree**

Bachelor

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

School of Rehabilitation Sciences, Hezar Jerib street

##### **City**

Isfahan

##### **Province**

Isfahan

##### **Postal code**

81746-73461

**Phone**

+98 31 3792 3071

**Fax**

**Email**

fatemehhh@rehab.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fatemeh Mehrabi

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

School of Rehabilitation Sciences, Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 3071

**Fax**

**Email**

fatemehhh@rehab.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Fatemeh Mehrabi

**Position**

Master student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

School of Rehabilitation Sciences, Hezar Jerib street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Phone**

+98 31 3792 3071

**Fax**

**Email**

fatemehhh@rehab.mui.ac.ir

## 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

All obtained data, such as demographic information and primary outcomes measured at all time points, and data analysis can be shared after unidentifiable subjects.

### When the data will become available and for how long

The access period begins after the results are published.

### To whom data/document is available

Anyone working in the medical and rehabilitation field can access the information.

### Under which criteria data/document could be used

After receiving information if they wish to use it in future studies, they should seek permission from the designers.

### From where data/document is obtainable

Postal address: School of Rehabilitation Sciences, Hezar Jerib street, Isfahan, Iran Postcode: 8174673461 Email address : fatemehhh@rehab.mui.ac.ir fmehrabipt@yahoo.com Phone Number : +98 31 3792 3071 Cell Number : 09139649659 Responsible person: Fatemeh Mehrabi

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

The applicant can request the data by email. After 5 working days the data will be sent to them.

### Comments