

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The efficacy of of purposeful strengthening exercises based on biomechanical defects on ultrasonographic parameters and kinematic variables in people with Patellofemoral Pain Syndrome

Protocol summary

Study aim

The efficacy of of purposeful strengthening exercises based on biomechanical defects on ultrasonographic parameters and Kinematic variables in people with Patellofemoral Pain Syndrome

Design

Clinical trial with an intervention group and a control group, with parallel groups, double blinded, randomly constructed, on 20 people in each group

Settings and conduct

In this study, eligible people will be included among the patients with patellofemoral pain syndrome and will be randomly divided into two intervention and control groups. Treatment interventions for each group will be carried out in eight weeks. Outcome assessment and data analysis will be performed by another colleague who is blinded to group assignment. Also, the patients will be blinded to the treatments of each group. Data collection tools will include visual analog scale, ultrasonography and motion analysis device.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with patellofemoral pain syndrome with lateral gliding patella, pain at least 3 on the visual analog scale, knee pain when running, jumping, sitting and standing up. Exclusion criteria: History of patella dislocation and knee surgery.

Intervention groups

Intervention group: specific strengthening exercises of the vastus medialis oblique muscle with routine physiotherapy treatments (stretching exercises, gluteal and quadriceps isometric exercises, electrotherapy including conventional tens). Control group: only routine physiotherapy treatments (stretching exercises, gluteal and quadriceps isometric exercises, electrotherapy including conventional tens). In both groups, the interventions will be conducted for eight weeks and three sessions per week.

Main outcome variables

Pain intensity; distance between patellar tip and trochlear groove; femoral sulcus angle; patella offset position; patella condylar distance; knee kinematic; hip kinematic.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048523N2**

Registration date: **2022-12-13, 1401/09/22**

Registration timing: **prospective**

Last update: **2022-12-13, 1401/09/22**

Update count: **0**

Registration date

2022-12-13, 1401/09/22

Registrant information

Name

Saeed Mikaili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8879 5422

Email address

saeed.mikaely@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-31, 1401/10/10

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of of purposeful strengthening exercises based on biomechanical defects on ultrasonographic parameters and kinematic variables in people with Patellofemoral Pain Syndrome

Public title

The effect of strengthening exercises on anterior knee pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with patellofemoral pain syndrome with lateral gliding patella Pain at least 3 on the visual analog scale Knee pain when running, jumping, sitting and standing up

Exclusion criteria:

History of patella dislocation History of knee surgery

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized method: balanced randomized blocks. Random concealment: sealed envelope. Randomization method: code of the intervention group: A code of the control group: B. Due to having two groups, the determined blocks are of four, so that the total number of possible permutations of four is 6, including: ABAB, ABBA, BAAB, BABA, AABBB, BBAA. To create a random sequence, we will number the possible blocks (6 blocks) from 1 to 6, we will select the block numbers from the random number table, and based on these numbers, we will determine the sequence of blocks in each group. According to the sample size of 40, 10 of these blocks are randomly placed together, each of these codes representing the treatment group of each patient is placed in a sealed envelope, then patients will be assigned to one of the envelopes in order of number. In this study, the unit of randomization is the individual.

Blinding (investigator's opinion)

Double blinded

Blinding description

The main researcher is blinded to the selection and randomization of participants, and assigning groups will be done by another colleague. Treatment for the intervention group will be done on even days of the week and treatment for the control group will be done on odd days of the week, so the participants will be blinded to their treatment and group assignment. Data collection and analysis after the completion of the interventions will be done by another colleague who is blind to group assignment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Research Ethic Committees of Vice Chancellor in Research Affairs Shahid Beheshti University of Medic

Street address

Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2021-07-11, 1400/04/20

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.217

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

Patellofemoral pain syndrome

ICD-10 code

M22.2

ICD-10 code description

Patellofemoral disorders

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

Pain intensity

Timepoint

Measurement of pain intensity at the beginning of the study (before the intervention), at the end of the study (8

weeks after the intervention) and 3 months after the intervention In the follow-up period.

Method of measurement

Visual Analog Scale

2

Description

Distance between patellar tip and trochlear groove

Timepoint

Measurement of distance between patellar tip and trochlear groove at the beginning of the study (before the intervention), at the end of the study (8 weeks after the intervention) and 3 months after the intervention In the follow-up period.

Method of measurement

Ultrasonography

3

Description

Femoral sulcus angle

Timepoint

Measurement of femoral sulcus angle at the beginning of the study (before the intervention), at the end of the study (8 weeks after the intervention) and 3 months after the intervention In the follow-up period.

Method of measurement

Ultrasonography

4

Description

Patella offset position

Timepoint

Measurement of patella offset position at the beginning of the study (before the intervention), at the end of the study (8 weeks after the intervention) and 3 months after the intervention In the follow-up period.

Method of measurement

Ultrasonography

5

Description

Patella condylar distance

Timepoint

Measurement of patella condylar distance at the beginning of the study (before the intervention), at the end of the study (8 weeks after the intervention) and 3 months after the intervention In the follow-up period.

Method of measurement

Ultrasonography

6

Description

Knee kinematic

Timepoint

Measurement of knee kinematic at the beginning of the study (before the intervention), at the end of the study (8 weeks after the intervention) and 3 months after the intervention In the follow-up period.

Method of measurement

Motion analysis device

7

Description

Hip kinematic

Timepoint

Measurement of hip kinematic at the beginning of the study (before the intervention), at the end of the study (8 weeks after the intervention) and 3 months after the intervention In the follow-up period.

Method of measurement

Motion analysis device

Secondary outcomes

1

Description

Level of functional disability

Timepoint

Measurement of level of functional disability at the beginning of the study (before the intervention), at the end of the study (8 weeks after the intervention) and 3 months after the intervention In the follow-up period.

Method of measurement

The knee injury and osteoarthritis outcome score

Intervention groups

1

Description

Intervention group: specific strengthening exercises of the vastus medialis oblique muscle with routine physiotherapy treatments (stretching exercises, gluteal and quadriceps isometric exercises, electrotherapy including conventional tens). The interventions will be conducted for eight weeks and three sessions per week.

Category

Rehabilitation

2

Description

Control group: Routine physiotherapy treatments (stretching exercises, gluteal and quadriceps isometric exercises, electrotherapy including conventional tens). The interventions will be conducted for eight weeks and three sessions per week.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Rehabilitation., Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Mohsen Roostayi

Street address

School of Rehabilitation., Shahid Beheshti University of Medical Sciences., Damavand St., Emam Hossein Sq

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1722

Email

mohsen42@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Shahid Beheshti University of Medical Sciences., Arabi Ave., Daneshjoo Blvd., Velenjak.

City

Tehran

Province

Tehran

Postal code

1983963113

Phone

+98 21 2243 9781

Email

zarghi@sbmu.ac.ir

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

Saeed Mikaili

Position

PhD candidate Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation., Shahid Beheshti University of Medical Sciences., Damavand St., Emam Hossein Sq

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 8863 1084

Email

saeed.mikaely@yahoo.com

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Khosro Khademi Kalantari

Position

Professor of Physiotherapy

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation., Shahid Beheshti University of Medical Sciences., Damavand St., Emam Hossein Sq

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 7756 1722

Email

khosro_khademi@yahoo.co.uk

Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeed Mikaili

Position

PhD candidate Physiotherapy

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

School of Rehabilitation., Shahid Beheshti University
of Medical Sciences., Damavand St., Emam Hossein
Sq

City

Tehran

Province

Tehran

Postal code

1616913111

Phone

+98 21 8863 1084

Email

saeed.mikaely@yahoo.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

All above will be published in the article.

When the data will become available and for how long

After the article publication

To whom data/document is available

Researchers and students in academic centers

Under which criteria data/document could be used

Other researchers and therapists in the rehabilitation
and medical field can use this use the data of this study
after the article publication.

From where data/document is obtainable

After the article publication, people can find the article
by searching in internet and access the data.

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

After the article publication, people can find the article
by searching in internet and access the data.

Comments