Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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Email address

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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, AABB, 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
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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
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School of Rehabilitation., Shahid Beheshti University of Medical Sciences., Damavand St., Emam Hossein Sq
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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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
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Saeed Mikaili
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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
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