Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of dry needling and functional joint mobilization with functional joint mobilization only on pain, disability and quality of life in patients with patellofemoral pain syndrome

Protocol summary

Study aim
Comparing the effects of functional mobilization with functional mobilization and dry needling in relation to pain, disability, quality of life and the effectiveness of treatment in people with patellofemoral joint pain syndrome

Design
The present clinical trial will have a control group, with parallel, double-blind, randomized groups on 56 patients. The closed envelope method will be used for randomization.

Settings and conduct
Physiotherapy clinic of Ghaem University Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: Aged between 18 and 40 years The diagnosis of this syndrome is based on pain behind the patella or around the patella, which occurs with at least two opposite activities including squatting, climbing stairs, going downstairs, sitting for a long time, and kneeling. Presence of at least one active trigger point. Have at least a score of 3 on the VAS pain scale. Exclusion criteria: History of knee surgery Patellar tendinopathy or osteoarthritis Symptoms of pressure on the lumbosacral nerve root History of injection, dry needling treatment of the quadriceps or knee muscles Any knee sports injury such as a meniscus tear or cruciate ligament injury Anticoagulant drugs usage Pregnancy Any structural problem on the lower limb Any peripheral or central neurological damage Diabetes Fear of needles Presence of bilateral femoral patellar pain

Intervention groups
Patients are divided into two groups: routine physiotherapy with dry needling and functional mobilization and routine physiotherapy with functional mobilization.

Main outcome variables
pain and function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221030056342N1**
Registration date: **2023-01-28, 1401/11/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-28, 1401/11/08**
Update count: **0**

Registration date
2023-01-28, 1401/11/08

Registrant information

Name
Afsaneh Zeinalzadeh

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3884 6710

Email address
zeinalzadehaf@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-01, 1401/09/10

Expected recruitment end date
2023-07-21, 1402/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of dry needling and functional joint mobilization with functional joint mobilization only on pain, disability and quality of life in patients with patellofemoral pain syndrome

Public title
Comparison of dry needling and functional joint mobilization with functional joint mobilization only on pain, disability and quality of life in patients with patellofemoral pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
The age of participants is between 18 and 40 years. The diagnosis of this syndrome is based on the pain behind the Patella or around the patella. Presence of at least one active trigger point. Have at least a score of 3 on the VAS pain scale.

Exclusion criteria:
History of knee surgery P Patellar tendinopathy or osteoarthritis, any systemic disease Symptoms of pressure on the lumbosacral nerve root If the participants had acupuncture, injection or dry needling treatment of the quadriceps or knee muscles in the last 6 months. knee sports injury such as meniscus tear or cruciate ligament injury If the participants use anticoagulant drugs, or have blood disorders or are pregnant. Any structural problem of the lower limb (such as arthritis or the presence of a prosthesis) Any peripheral or central neurological damage or chronic disease such as diabetes Any Fear of needles resence of bilateral patellofemoral pain syndrome.

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

Gender
Both

Phase
N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
Blocked randomization will be done using random block method. Using the Sealedenvelope.com website, a sequence of 28 letters consisting of letters a and b will be placed in opaque, sealed envelopes, respectively. When the patients visit, the envelopes are taken from the collection of envelopes and according to the order determined by the number on the back of the envelopes, the sample allocator (department secretary) after obtaining informed consent, opens the envelope and assigns the patient to the relevant group. The secretary of the department is also unaware of how to code.

Blinding (investigator's opinion)
Double blinded

Blinding description
The allocator is the secretary of the physiotherapy department and does not know how to code. Also, the evaluator and statistical analyst are not aware of the way of grouping. Allocation Concealment method: closed, opaque, and sealed envelopes and numbered in order

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Paramedical Sciences and Health School

Street address
Khorasan Razavi, Mashhad, Shaheed Fakuri Blvd, between Shahidjovan and Al Shahidi Square, Danesh and Salamat Shahrek

City
Mashhad

Province
Razavi Khorasan

Postal code
91778-97165

Approval date
2022-07-30, 1401/05/08

Ethics committee reference number
IR.MUMS.FHMPM.REC.1401.088

Health conditions studied

1

Description of health condition studied
Patella Femoral Pain Syndrome

ICD-10 code
M22.2X

ICD-10 code description
Patellofemoral disorders

Primary outcomes

1

Description
Pain

Timepoint
Visual Analogue scale

Method of measurement
In this scale, there is a horizontal line of 10 cm. The left end of this line corresponds to the absence of pain and

the other end corresponds to the most intense pain that a person experiences. The distance between the two ends is calculated in centimeters and is calculated as the pain intensity.

2

Description
Performance
Timepoint
Persian version of Kujala questionnaire
Method of measurement
It is used to assess the functional activity of the knee during movements that potentially stress the knee joint. This questionnaire contains 13 items that are completed by the participant. The scoring range of this questionnaire is from zero to one hundred. Higher scores indicate lower levels of disability, and zero means the most severe disability. The Persian version of this questionnaire has been localized and validated for patients with patellofemoral pain syndrome.

Secondary outcomes

1

Description
Quality of Life
Timepoint
Before and after of treatment
Method of measurement
Persian questionnaire SF36

2

Description
The effectiveness of treatment
Timepoint
Before and after of treatment
Method of measurement
Global Rating Scale

Intervention groups

1

Description
Intervention group: At first, they receive conventional physiotherapy. Exercises are applied in 3 sets with 10 repetitions. The cold pack is applied for 15 minutes after the sessions. Physiotherapy takes place for 12 sessions and 3 times a week. Patients will be taught knee and thigh strengthening exercises at home and exercise brochures will be provided to them. In addition to these, neuromuscular electrical stimulation is used for patients, in which the patient contracts his quadriceps muscle simultaneously with the electrical current. Two surface adhesive electrodes are attached to the movement points of the quadriceps: on the vestus medialis and the vestus lateralis. During the application of neuromuscular electrical stimulation, the patient performs two types of movements: 1. Isometric quadriceps strengthening (30 isometric exercises) 2. Then Terminal knee extension from zero to 30 degrees (30 isotonic exercises).
Category
Rehabilitation

2

Description
Intervention group: Functional mobilization is the second intervention, which includes movement of the patella and movement of internal rotation of the tibia in relation to the femur, first in a less functional and non-weight bearing state, then in a weight bearing state, while bending and straightening the knee, standing, squatting, and on the stairs.
Category
Rehabilitation

3

Description
Intervention group: The third intervention is the use of dry needling for the quadriceps muscles in the trigger pain points that are detected by the physiotherapist during the manual examination.
Category
Rehabilitation

4

Description
Control group: At first, they receive conventional physiotherapy. Exercises are applied in 3 sets with 10 repetitions. The cold pack is applied for 15 minutes after the sessions. Physiotherapy takes place for 12 sessions and 3 times a week. Patients will be taught knee and thigh strengthening exercises at home and exercise brochures will be provided to them. In addition to these, neuromuscular electrical stimulation is used for patients, in which the patient contracts his quadriceps muscle simultaneously with the electrical current. Two surface adhesive electrodes are attached to the movement points of the quadriceps: on the vestus medialis and the vestus lateralis. During the application of neuromuscular electrical stimulation, the patient performs two types of movements: 1. Isometric quadriceps strengthening (30 isometric exercises) 2. Then Terminal knee extension from zero to 30 degrees (30 isotonic exercises).
Category
Rehabilitation

5

Description
Control group: Functional mobilization is the second intervention, which includes movement of the patella and movement of internal rotation of the tibia in relation to the femur, first in a less functional and non-weight bearing state, then in a weight bearing state, while bending and straightening the knee, standing, squatting, and on the stairs.
Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Physical Therapy Clinic of Qaem Hospital

Full name of responsible person
Mr. Javad Zarandi

Street address
Narjes building, first floor, Physiotherapy Department, Qaem Hospital, Nurse Street.

City
Mashhad

Province
Razavi Khorasan

Postal code
9176699199

Phone
+98 51 3841 1538

Email
zarandiMJ1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Majid Ghayour Mobarhan

Street address
Ghoreshi Building, Doctora Crossroad.

City
Mashhad

Province
Razavi Khorasan

Postal code
9919191778

Phone
+98 51 3841 1538

Email
vcresearch@mums.ac.ir

Grant name
Mashhad University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Zohre Khorshidi

Position
MSc Colleague

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
Faculty of Paramedical Sciences, University campus, East entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad.

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948964

Phone
+98 51 3869 8719

Email
Zohreh.khorshidi7@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Zohreh Khorshidi

Position
MSc Colleague

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

Street address
Faculty of Paramedical Sciences, University campus, East entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad.

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948964

Phone
+98 51 3869 8719

Email
Zohreh.khorshidi7@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Zohreh Korshidi
Position
MSc Colleague
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Faculty of Paramedical Sciences, University campus, East entrance of Ferdowsi University of Mashhad, Azadi Square, Mashhad.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948964
Phone
+98 51 3869 8719
Email
Zohreh.khorshidi7@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All data will be reported in the form of a research article. Raw data will be delivered to researchers for meta analysis.
When the data will become available and for how long
6 months after publication
To whom data/document is available
For researchers only
Under which criteria data/document could be used
For meta-analysis Only
From where data/document is obtainable
zeinalzadehAF@mums.ac.ir
What processes are involved for a request to access data/document
The response will be sent 3 within months after considering the researcher's request.
Comments