

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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.korshidi7@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