

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of neurodynamic mobilization and dry needling technique on the pain, function, and range of motion in subjects with patellofemoral pain syndrome

Protocol summary

Study aim

The present study is designed to investigate the effect of neurodynamic mobilization techniques and dry needling on pain, function and knee range of motion in patients with patellofemoral syndrome.

Design

A clinical trial with a control group, double-blind, randomized, is performed on 120 patients. Block randomization is used for randomization.

Settings and conduct

Subjects are assigned to four groups of control, DN and Neurodynamic, and a combination of these two techniques according to block randomization. The two-blind study will be conducted in such a way that people are assigned to groups and patients are evaluated by people who are unaware.

Participants/Inclusion and exclusion criteria

All participants are between 18 and 40 years old and have a clinical diagnosis of patellofemoral syndrome. Clark's test is positive in these patients and the pain is in one knee. There are constant pain for at least the last 4 weeks. Also, they have trigger points in the gluteus medius and quadriceps muscles on the same side and quadratus lumborum on the opposite side. People are excluded from the study if they have a history of previous knee surgery, any knee pathology (meniscal tear, patella tendinopathy, ligament sprain and osteoarthritis), any systemic disease and/or connective tissue disorders.

Intervention groups

Dry needling (DN): It is used on the trigger point in the lumbar and knee muscles. The needle is applied for three sessions with an interval of one day. Neurodynamic technique: The technique of neurodynamic mobilization of the femoral nerve is performed in two tension and slide modes three sessions a week for two weeks. Control group: After the trigger points are determined,

the therapist applied soft and superficial massage on the involved muscles.

Main outcome variables

1. Pain intensity
2. Disability index
3. Step down test
4. Knee range of motion

General information

Reason for update

The information of the start and end of sampling was not recorded correctly and it was corrected.

Acronym

patellofemoral pain syndrome (PFPS)

IRCT registration information

IRCT registration number: **IRCT20240211060958N2**

Registration date: **2024-06-02, 1403/03/13**

Registration timing: **prospective**

Last update: **2024-08-02, 1403/05/12**

Update count: **1**

Registration date

2024-06-02, 1403/03/13

Registrant information

Name

tahereh rezaeian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5367

Email address

tahere.rezaiyan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-21, 1403/04/01
Expected recruitment end date
2024-12-20, 1403/09/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of neurodynamic mobilization and dry needling technique on the pain, function, and range of motion in subjects with patellofemoral pain syndrome

Public title
effect of neurodynamic mobilization and dry needling technique in subjects with patellofemoral pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All participants are aged from 18 to 40 years Having a clinical diagnosis of patellofemoral syndrome. Complaints of pain in the anterior of the knee or around the patella on the affected side are determined during at least 3 of the following activities: squatting, step up and down from stairs, running, prolonged sitting, and kneeling. Positive Clark test Unilateral pain in one knee having constant pain for at least the last 4 weeks and the average pain in the last week is more than 3 according to the NPRS scale. The present of trigger points in the gluteus medius and quadriceps muscles on the same side and quadratus lumborum on the opposite side.

Exclusion criteria:

History of previous knee surgery Any knee pathology (meniscus tear, patella tendinopathy, ligament sprain and osteoarthritis) Any systemic diseases and/or connective tissue disorders People who have received acupuncture, injections, or dry needling treatment for knee in the past 6 months. Pregnant women

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization: A table of random numbers is used. Participants are given a number and using the table of random numbers. Therapist randomly starts from a table point in the row or column direction. The

therapist can close his eyes and choose a point.

Blinding (investigator's opinion)

Double blinded

Blinding description

Double-blind study will be done ,in this way, the assessment of patients are done by people who are unaware of the status of the grouping of patients. Treatment is provided by a specialist physiotherapist and evaluated by a collaborator.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the kerman University of Medical Sciences

Street address

Haft Bagh Square, Kerman University of Medical Sciences

City

Kerman

Province

Kerman

Postal code

7616913555

Approval date

2024-02-08, 1402/11/19

Ethics committee reference number

IR.KMU.REC.1402.345

Health conditions studied

1

Description of health condition studied

patellofemoral pain syndrome

ICD-10 code

M25.56

ICD-10 code description

Pain in knee

Primary outcomes

1

Description

Pain intensity

Timepoint

Before, After and 1month follow up

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

Knee disability index

Timepoint

Before, After and 1month follow up

Method of measurement

kujala questionnaire

2

Description

Step down test

Timepoint

Before, after and 1month follow up

Method of measurement

Functional test: Participants are asked to stand on the step with their injured foot, try to touch the ground with the opposite heel, and then return to their original position.

3

Description

Knee range of motion

Timepoint

Before, after and 1month follow up

Method of measurement

Goniometer

Intervention groups

1

Description

Intervention group: Dry needling. The treatment is done in 3 sessions with an interval of one day. The muscles selected for dry needling in this study are practically important in the management of patellofemoral syndrome, including: quadratus lumborum, gluteus medius, iliopsoas, rectus femoris, vastus medialis, and vastus lateralis.

Category

Rehabilitation

2

Description

Intervention group: Neuromobilization of femoral nerve
The patient is placed in a sidelying position on the side of the healthy leg. The lower limb on the healthy side is placed at 90 degrees of hip flexion and knee flexion. The lower limb of the affected side is placed in a neutral hip position, and the trunk is in a straight position and the head is in a neutral position. The therapist stands behind the patient at the level of the pelvis so that the pelvis does not move forward or backward. Then we ask the patient to actively move neck and trunk flexion, knee extension to neck and trunk extension, knee flexion.

Category

Rehabilitation

3

Description

Control group: Placebo While the patient is supine position, the therapist applies soft and superficial massage on the involved muscles. The fingertips of each therapist's hand are placed in contact with the related muscles and a surface massage is performed. The number of sessions is the same as the dry needling group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Medical centers affiliated to Kerman University of Medical Sciences

Full name of responsible person

Majid Ashraf Ganjavi

Street address

Tehran Road, under the railway bridge, Red Crescent Street

City

Kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3212 4962

Email

tahere.rezaiyan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abedin Iranpour

Street address

The beginning of Haft Bagh Alavi axis, Kerman University of Medical Sciences campus

City

kerman

Province

Kerman

Postal code

7616913555

Phone

+98 34 3132 5700

Email

a.iranpour@kmu.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
tahereh rezaeian
Position
Assistant Professor of Kerman University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
The beginning of Haft Bagh Alavi axis, Kerman University of Medical Sciences
City
kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5700
Email
tahere.rezaiyan@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
tahereh rezaeian
Position
Assistant Professor of Kerman University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address

The beginning of Haft Bagh Alavi axis, Kerman University of Medical Sciences
City
kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5700
Email
tahere.rezaiyan@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
tahereh rezaeian
Position
Assistant Professor of Kerman University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Physiotherapy
Street address
The beginning of Haft Bagh Alavi Square, Kerman University of Medical Sciences
City
kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5700
Email
tahere.rezaiyan@gmail.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
Some of the data, such as information about the consequences, can be shared
When the data will become available and for how long

Starting the access period: 6 months after publication the results

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

Only statistical analyses can be used to find treatment for improvement of patients

From where data/document is obtainable

Applicants can be guided by email to the authors(tahere.rezaiyan@gmail.com).

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

First, they will email the authors of the study and we will be answered within a week

Comments