

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

"Investigation of the effect of adding femoral nerve neurodynamic technique to routine physiotherapy treatment compared to routine physiotherapy treatment alone, on pain and functional disability of patients with patellofemoral pain syndrome"

Protocol summary

Study aim

Comparison of average change of pain, functional disability and range of motion of hip extension in patients with patellofemoral pain syndrome after intervention between two treatment groups

Design

A clinical trial with intervention and control groups will be conducted in parallel, single-blind, randomized block allocation using the WWW.Sealedenvelop.com site on 66 patients.

Settings and conduct

After patients with patellofemoral pain syndrome are admitted to the Omid physiotherapy clinic and are divided into two intervention groups (receiving routine physiotherapy treatment with femoral nerve neurodynamic technique) and control (receiving routine physiotherapy treatment) the study will be conducted. Due to the similarity of the femoral nerve neurodynamic technique to the stretching techniques of the lower limb muscles, the participants are blinded to the type of treatment, as a result of the study, a blind strain will be designed.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1. Being between 18 and 45 years old
2. Worsening of symptoms in at least two cases: squatting, going up and down stairs, kneeling or sitting for a long time
3. Positive at least two of the tests: Clark, compression test, and active patellar grind test
Exclusion criteria : 1. Having a specific injury in the meniscus or ligaments of the knee
2. History of surgery in the lower limbs or spine
3. Having limited movement in the spine, knee, or hip
4. Having hypermobile joints
5. Having acute back pain
6. Malignancies
7. Having a systemic disease such as rheumatic disease
8. Report severe pain of more than 7.4 on the VAS scale

Intervention groups

Intervention group: receiving routine physiotherapy treatment with femoral nerve mobilization
Control group: receiving routine physiotherapy treatment

Main outcome variables

intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230620058541N1**

Registration date: **2023-08-01, 1402/05/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-01, 1402/05/10**

Update count: **0**

Registration date

2023-08-01, 1402/05/10

Registrant information

Name

Romina Gerami

Name of organization / entity

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2024-01-01, 1402/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

"Investigation of the effect of adding femoral nerve neurodynamic technique to routine physiotherapy treatment compared to routine physiotherapy treatment alone, on pain and functional disability of patients with patellofemoral pain syndrome"

Public title

"The effect of femoral nerve neurodynamic technique on pain and functional disability in patients with patellofemoral pain syndrome"

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being between 18 and 45 years old Worsening of symptoms in at least two of the following: squatting, going up and down stairs, kneeling, or sitting for long periods. Positive at least two tests: Clark, compression test, and active patellar grind

Exclusion criteria:

Having specific injuries in the meniscus or ligaments of the knee History of lower limb or spine surgery Having limited range of motion in the spine, knee, or hip Having hypermobile joints (score above 4 on the Beighton scale) Having acute back pain (root L2/L3/L4) Malignancies Having a systemic disease such as rheumatic disease Report severe pain more than 7.4 on the VAS scale

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

The block random allocation method was designed by an epidemiologist using WWW.Sealedenvelop.com. The number of considered blocks is 6. The list of random allocation of patients will only be at the disposal of the plan's epidemiologist. To hide the random allocation process, the order of the treatments is written on 84 cardboard cards that are the identification number of the corresponding treatment and only the project methodologist will be aware of the corresponding code. The cards are placed in envelopes (the envelopes are

thick and it is not possible to see from the back of the envelope). When the therapist declares the eligibility of a patient, the methodologist will provide the patient with the treatment package. The person evaluating the intended outcomes is a third person who is unaware of the randomization process and the type of treatment performed. To analyze the data, a statistician who is separate from the study process and is unaware of all the processes will be used.

Blinding (investigator's opinion)

Single blinded

Blinding description

After the participants enter the study, they are given a general explanation of the study process. Due to the single-blind design of the study, the participants are blinded to receiving the relevant intervention type. Since the implementation of neurodynamic techniques is similar to the implementation of the muscle stretching technique and both groups benefit from the implementation of the muscle stretching technique, it is not possible to differentiate the technique by the participants. Also, in this study, the person analyzing the results is blind to the type of treatment and does not know the type of treatment of the patients.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Babol University of Medical Sciences

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Babol University of Medical Sciences, Keshavars boulevard

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4717647745

Approval date

2023-06-19, 1402/03/29

Ethics committee reference number

IR.MUBABOL.HRI.REC.1402.020

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

Patellofemoral Pain Syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity of patients with patellofemoral pain syndrome

Timepoint

The beginning of the study (before the start of the intervention) and the end of the intervention (at the end of the 10th session)

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Functional disability of patients with patellofemoral pain syndrome

Timepoint

The beginning of the study (before the start of the intervention) and the end of the intervention (the end of the 10th session)

Method of measurement

Kujala's 13-question questionnaire

2

Description

Hip extension range in the slump position of patients with patellofemoral pain syndrome

Timepoint

The beginning of the study (before the start of the intervention) and the end of the intervention (the end of the 10th session)

Method of measurement

Goniometer

Intervention groups

1

Description

Control group: This group of patients only receives the usual physiotherapy treatment, which includes: 1. Electrotherapy: To reduce pain, a 4-channel conventional tenniss device with a frequency of 60-120 Hz and a diversion of 20-60 microseconds is used. 2. Therapeutic exercise: includes strengthening and stretching exercises. Stretching: Stretching exercises include stretching the hamstrings, gastrosoleus, iliotibial band, and quadriceps muscles. Each stretching exercise is performed 3 times and the stretching position is maintained for 30 seconds each time. Strengthening with a specific dose is performed by the patient. 1) isometric quadriceps contraction in the supine position (2 times a day, 20 repetitions each time) 2) SLR (2 times a day, 10

repetitions each time) 3) knee extension in the sitting position (2 times) 5 repetitions per day (4) Hip abduction in a standing position (2 times a day, 5 repetitions each time) 5) External rotation of the hip in a standing position (2 times a day, 5 repetitions each time) Strengthening exercise of the first session, only quadriceps isometric contraction In the second session, a set of SLR and knee extension is added in the sitting position, in the third session, a set of hip abduction and external rotation exercises is added, and from the fourth session onwards, the patient has prescribed a complete set of exercises. The intervention is carried out in 10 sessions (5 days a week) and after that, the studied variables, i.e. pain intensity, functional disability, and range of motion of hip extension are measured again during the neurodynamic technique.

Category

Rehabilitation

2

Description

Intervention group: This group of patients, after receiving the usual physiotherapy treatment that was completely given in the control group, will also receive the neurodynamic technique of the femoral nerve as follows. To perform the neurodynamic technique: 1. The nerve stretching movement is used, including stretching along the entire length of the nerve path, which tries to apply tension along the entire nerve axis. In the case of the femoral slump technique, head, neck, and trunk flexion and hip extension (nerve tension) are in the neutral position of head, neck and trunk, and hip flexion. 2. The movement of sliding the nerve along its bed without stretching the nerve. Regarding the femoral slump technique, it is done in two ways: Proximal sliding is a position where the patient's hip is kept in flexion, and the patient's head, neck, and trunk are flexed and returned to the neutral position. Distal sliding, maintaining the head, neck, and trunk extension position, we take the patient's hip to the extension position and return to the neutral position again. The neurodynamic techniques of the femoral nerve are performed in 3 sets of 10 with 10 seconds of rest between sets. The onset of symptoms of people is in the form of reports of neurogenic pain (sharp pain and tingling) in the buttock and front of the thigh. The intervention is carried out in 10 sessions (5 days a week) and after that, the studied variables, i.e. pain intensity, functional disability, and range of motion of hip extension are measured again during the neurodynamic technique.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid Clinic

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Vice President of Research and Technology of Babol
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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

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Gerami Romina

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Maryam Abbaszadeh -Amirdehi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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 data related to participants in the plan can be shared
after de-identification.

When the data will become available and for how long

The access period starts after the results are printed

To whom data/document is available

All individuals are allowed to access the data for
research purposes.

Under which criteria data/document could be used

The data can be accessed for research purposes by
sending an email to the responsible author.

From where data/document is obtainable

To receive data, please use the postal address
r.gerami@mubabol.ac.ir or phone number 01132194641
and the address Keshavarz Blvd., Babol University of
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What processes are involved for a request to access data/document

To receive information, it is enough to send the reason
for the need to access the data to the first author's
email, or call 01132194641, or visit Keshavarz Blvd.,
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Comments