

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the added effects of popliteus muscle dry needling to exercise therapy on knee pain, function and proprioception knee joint in patient with patellofemoral pain syndrome: A randomized clinical trial

Protocol summary

Study aim

Investigating the added effects of popliteus muscle dry needling to exercise therapy on knee pain function and proprioception knee joint in patient with patellofemoral pain syndrome

Design

A controlled, double group, single blinded (assessor) randomized clinical trial on 36 patients. For randomization permutational randomization method with the number of 9 blocks and the block size of 4 is used

Settings and conduct

People of two groups are selected from patients with patellofemoral pain syndrome. People in one group receive exercise therapy (for 4 weeks, 3 times a week) and people in the other group receive dry needling of the popliteus muscle (4 times) in addition to exercise therapy. The assessor and the therapist are not the same person, in this way the assessor will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: People between the ages of 18 and 40
Complaints of anterior knee pain in at least 2 cases of daily activities
Clark's test is positive
Duration of the onset of pain is more than a month and the pain is unilateral in front of, around or behind the patella
Kujala score level 50-80 with moderate disability
Exclusion criteria: Presence of knee joint injuries
History of surgery and trauma in the entire lower limb in the last 6 months,
Lower limb neurological disorders and neuropathic pain
People who have received physical therapy and dry needling for patellofemoral pain in the past 6 months
Pain radiating from the lumbar region
Contraindications to using dry needling

Intervention groups

In the first group, participants receive dry needling of the popliteus muscle and exercise therapy and in the second group participants receive only exercise therapy

Main outcome variables

NRS, Kujala questionnaire, knee joint position sense

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241004063260N1**

Registration date: **2024-10-24, 1403/08/03**

Registration timing: **prospective**

Last update: **2024-10-24, 1403/08/03**

Update count: **0**

Registration date

2024-10-24, 1403/08/03

Registrant information

Name

Farzaneh Yazdani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3212 2600

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-10, 1403/08/20

Expected recruitment end date

2025-05-10, 1404/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the added effects of popliteus muscle dry needling to exercise therapy on knee pain, function and proprioception knee joint in patient with patellofemoral pain syndrome: A randomized clinical trial

Public title

The effect of adding popliteus muscle dry needling to exercise therapy on the symptoms of patients with patellofemoral pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People between the ages of 18 and 40 (both gender)
Complaints of anterior knee pain in at least 2 cases of daily activities including: prolonged sitting, going up and down stairs, squatting, kneeling, jumping and running
Clark's test is positive
The duration of the onset of pain is more than a month and the pain is unilateral in front of, around or behind the patella, when the person reports an average pain of 4-7 on a numerical scale in the last week, and if the pain is bilateral, consider the side that has more pain
Kujala score level 50-80 with moderate disability

Exclusion criteria:

Presence of knee joint injuries such as meniscus tears or knee ligaments and tendons, knee joint arthrosis, dislocation or semi dislocation of the patella
History of surgery and trauma in the entire lower limb in the last 6 months
Lower limb neurological disorders and neuropathic pain
People who have received physical therapy and dry needling for patellofemoral pain in the past 6 months
Pain radiating from the lumbar region
Contraindications to using dry needling: - Presence of metabolic diseases including diabetes, rheumatic diseases - Local or systemic infection - Local wound in the skin - Pregnancy - Respiratory and cardiovascular problems (peripheral vascular disease, cancer, hepatitis, AIDS and any malignancy)) - taking immunosuppressive drugs - needle phobia - epilepsy and mental problems - suffering from bleeding diseases and taking anticoagulant drugs

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **36**

Randomization (investigator's opinion)

Randomized

Randomization description

Using the randomizer software with the help of

permutational randomization, 36 numbers are considered for each case and the software defines 9 blocks of 4.

Blinding (investigator's opinion)

Single blinded

Blinding description

The assessor who evaluates the variables is blind to the placement of people in each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Shiraz University of Medical Sciences

Street address

Ethics committee, Research and Technology Vice-Chancellor, 7th floor, central building of Shiraz university of Medical sciences

City

Shiraz

Province

Fars

Postal code

7198754361

Approval date

2024-08-28, 1403/06/07

Ethics committee reference number

IR.SUMS.REHAB.REC.1403.009

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**

Function

Timepoint

before the start of the intervention, after the intervention and two weeks after the intervention

Method of measurement

Secondary outcomes

1

Description

Pain

Timepoint

Before the start of the intervention, after the intervention and two weeks after the intervention

Method of measurement

Numeric Pain Rating Scale

2

Description

Proprioception

Timepoint

Before the start of the intervention, after the intervention and two weeks after the intervention

Method of measurement

Biodex isokinetic dynamometer device

Intervention groups

1

Description

Intervention group: Dry needling of the popliteus muscle with exercise therapy

Category

Treatment - Other

2

Description

Control group: Exercise Therapy

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Rehabilitation School, Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Yazdani

Street address

Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard

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7194815644

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mohammad-Hashem Hashempour

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Research and Technology Vice-Chancellor, 7th floor, Central building of Shiraz, Zand street

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Yazdani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information collection form including primary and
secondary outcomes, informed consent form and SPSS
file

When the data will become available and for how long

After the publication of the results of the study

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

Only for recording information in scientific databases

From where data/document is obtainable

Correspondence with the project manager by email
yazdani_far@sums.ac.ir

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

Maximum one month after sending the request by email

Comments