Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 6months 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 assesor 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

Kujala questionnaire

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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad-Hashem Hashempour
Street address
Research and Technology Vice-Chancellor, 7th floor, Central building of Shiraz, Zand street
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7134814336
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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
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Other areas of specialty/work
Physiotherapy
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School of Rehabilitation Sciences, Shahid Doran Campus, after Amir-al-momenin Burn Accident Hospital, Sadra Town Road
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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