Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Added value of multifidus dry needling in improving pain and function in females with patellofemoral pain: A randomized clinical trial study

Protocol summary

Study aim
Added value of multifidus dry needling in improving pain and function in females with patellofemoral pain

Design
A controlled, double group, single blinded (assessor), randomized (Randomizer site), phase 3 clinical trial on 60 patients.

Settings and conduct
The study at Shiraz's School of Rehabilitation Sciences will will investigate on the added value of multifidus dry needling in improving pain and function in females with patellofemoral pain.The experimental group received dry needling (DN) of the lumbar multifidus and quadriceps, and the control group received DN of the quadriceps only, three days per week for one week. Blinding of evaluator is maintained by separating treatment and assessment roles.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Non-traumatic anterior knee pain (≥3 months), age 18–40, pain intensity (NPRS) 3–6 in the past week, pain during ≥2 patellofemoral loading activities, positive Clarke’s sign, and Kujala score <80. Exclusion Criteria: Osteoarthritis; ligament/meniscus injury; patellar instability; plica syndrome; Osgood-Schlatter or Sinding-Larsen-Johansson syndrome; structural deformities or known pathology in the lower back, hip, or ankle; metabolic/neurological diseases (e.g., diabetes, radicular pain); contraindications to DN (cardiovascular disease, coagulopathy, anticoagulants, pregnancy, cancer, needle phobia); physiotherapy for knee pain in the past year; knee surgery history; acupuncture/injection/DN to knee or quadriceps in the past 6 months; bleeding disorders; or central/peripheral neurological pathology.

Intervention groups
Participants in the intervention group will receive DN targeting both the lumbar multifidus and quadriceps femoris muscles.The other group recieve only quardriceps femoris DN.

Main outcome variables
Pain intensity, Physical function, Pressure Pain Threshold

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250629066291N4**
Registration date: **2026-06-04, 1405/03/14**
Registration timing: **prospective**

Last update: **2026-06-04, 1405/03/14**
Update count: **0**

Registration date
2026-06-04, 1405/03/14

Registrant information
Name
Farzaneh Haghighat
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Not yet recruiting
Funding source

Expected recruitment start date
2026-06-20, 1405/03/30
Expected recruitment end date
2027-01-20, 1405/10/30
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Added value of multifidus dry needling in improving pain and function in females with patellofemoral pain: A randomized clinical trial study

Public title
Added value of multifidus dry needling in improving pain and function in females with patellofemoral pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range: 18 to 40 years Complaint of anterior knee pain (pain around or behind the patella) that was not related to trauma and had persisted for at least 3 months. The intensity of knee pain in the past week, according to the Numeric Pain Rating Scale (NPRS), reported by the patient: between 3 and 6 Report of pain during at least two load-bearing activities on the patellofemoral joint, including: ascending or descending stairs, squatting, prolonged sitting with the knee flexed, jumping activities, and running Positive Clarke's sign test Score on the Kujala Anterior Knee Pain Scale (AKPS): less than 80 Completion of the informed consent form

Exclusion criteria:
Osteoarthritis Ligament or meniscus injury Patellar instability, plica syndrome, Osgood-Schlatter disease, and Sinding-Larsen-Johansson syndrome Obvious structural deformities and known pathological conditions in the lower back, hip, and ankle Diagnosis of metabolic or neurological diseases such as diabetes or radicular pain Contraindications for dry needling, such as cardiovascular disease, coagulation disorders, use of anticoagulant medications, pregnancy, cancer, or needle phobia Receiving physiotherapy for knee pain within the past year History of knee surgery Receiving acupuncture, injection, or dry needling therapy for the knee or quadriceps muscles within the past 6 months Medical history of bleeding disorders Presence of central or peripheral neurological pathology

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

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The random assignment method in this study will be the blocked permutation method (number of blocks 8 and block size 4) which will be generated using randomizer site. The samples will be assigned in a 1:1 ratio. Opaque, sealed envelopes will be used to conceal the assignment.

Blinding (investigator's opinion)
Single blinded

Blinding description
The individual who performs the assessments is separate from the one who administers the treatments, and neither is aware of the other's work. The person responsible for randomization is also independent from both of the aforementioned individuals.

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, Zand Street

City
shiraz

Province
Fars

Postal code
7198754361

Approval date
2026-03-11, 1404/12/20

Ethics committee reference number
IR.SUMS.REC.1405.127

Health conditions studied

1

Description of health condition studied
Unilateral Patellofemoral pain

ICD-10 code
M22.2X9

ICD-10 code description
Patellofemoral disorders, unspecified knee

Primary outcomes

1

Description
pain intensity

Timepoint
Before intervention; One day after intervention period

Method of measurement
Numeric Pain Rating Scale (NPRS)

2

Description
Physical Function
Timepoint
Before intervention; One day after intervention period
Method of measurement
Kujala Questionnaire (Anterior Knee Pain Scale, AKPS)- step down - mSEBT

3

Description
Pressure Pain Threshold
Timepoint
Before intervention; One day after intervention period
Method of measurement
Algometer

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:In the intervention group, dry needling of the lumbar multifidus and quadriceps femoris muscles will be performed three days per week (on alternate days) for one week. Dry needling will be administered by an experienced and trained physiotherapist. Throughout the treatment, a “clean technique” will be employed, which includes handwashing, the use of non-latex examination gloves, and skin preparation with an alcohol swab prior to needle insertion.With the participant lying in a relaxed prone position, the multifidus muscle will be palpated in the region immediately lateral and adjacent to the interspinous spaces of the L4/L5 and L5/S1 vertebral levels, as determined by the examiner. To locate the L4/L5 and L5/S1 levels, the L4 vertebral level will first be identified by palpating the bilateral iliac crests, then tracing the intercristal line posterior-medially to its intersection with the lumbar spine. This intersection point is considered the L3/L4 interspinous space. The examiner will then palpate caudally to identify the L4/L5 and L5/S1 interspinous spaces, thereby determining the L4/L5 and L5/S1 vertebral levels. (It should be noted that these anatomical landmarks can vary between individuals, which may present a significant challenge for precise vertebral level identification via palpation.)To detect the presence of myofascial trigger points—defined as palpable, painful nodules within muscle tissue (whether active or latent)—the identified sites will be treated with dry needling. While each participant remains in the prone position, a solid, sterile, single-use needle will be inserted bilaterally into the lumbar multifidus muscles at the L3, L4, and L5 vertebral levels. Needle size (either 0.25 × 50 mm or 0.25 × 40 mm; Dongbang Medical, Korea) will be selected based on the participant’s body habitus.
Category
Treatment - Other

2

Description
Control group: In the control group, dry needling of the quadriceps femoris muscle alone will be administered as same as intervention group three days per week (on alternate days) for a total of one week.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Rehabilitaion School, Shiraz University of Medical Sciences
Full name of responsible person
Farzaneh Haghighat
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Hamid Mohammadi
Street address
Research and Technology Vice-Chancellor, 7th floor, Central building of Shiraz University of Medical Sciences, 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 Haghighat
Position
Assistant Professor
Latest degree
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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
Undecided - It is not yet known if there will be 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 outcomes, informed consent form and SPSS file
When the data will become available and for how long
After publication 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.

Haghighat_fa@yahoo.com

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

Maximum one month after sending the request by email

Comments