

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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 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 receive only quadriceps 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)

Phone

+98 71 3230 5410

Email address

haghighat_fa@yahoo.com

Recruitment status

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 intercrystal 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 Rehabilitation School, Shiraz University of
Medical Sciences

Full name of responsible person

Farzaneh Haghighat

Street address

Mehr Building, Shahid Chamran Hospital, Shahid
Chamran Boulevard

City

shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3624 0101

Email

rehabdep@sums.ac.ir

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

City

shiraz

Province

Fars

Postal code

7134814336

Phone

+98 71 3212 2430

Email

vcrdep@sums.ac.ir

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

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard

City

shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3624 0101

Email

haghighat_fa@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Haghighat

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard

City

shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3624 0101

Email

haghighat_fa@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Haghighat

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

Street address

Mehr Building, Shahid Chamran Hospital, Shahid Chamran Boulevard

City

shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3624 0101

Email

haghighat_fa@yahoo.com

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