Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the effect of acupuncture on pain and function in patients with patellofemoral pain syndrome: a clinical trial study

Protocol summary

Study aim
Determining the effect of acupuncture on pain and function in patients with patellofemoral pain syndrome

Design
A controlled, double-blind, randomized, phase 2 clinical trial with parallel groups on 50 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
Patients with patellofemoral knee pain syndrome referred to the sports clinic of Tehran Rasoul Akram Hospital Complex (PBUH) will be divided into two intervention and control groups. The intervention group will receive real acupuncture, and the control group will receive sham acupuncture. Functional tests will be performed immediately, one month, and three months after treatment to compare the results of the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 35 years, diagnosis of unilateral patellofemoral syndrome based on at least 5 of the 7 listed symptoms (pain produced by at least two of the following four tests: (i) isometric muscle contraction with slight knee flexion, (ii) patellofemoral joint line palpation, (iii) patellar compression against femur (IV) active resisted knee extension, absence of other knee joint injuries, Exclusion criteria: no history of knee trauma, intra-articular injection or physiotherapy within the last 3 months or surgery, no use of non-steroidal anti-inflammatory drugs within 15 days before the start of treatment, full cooperation for the study, history of knee locking and patellar dislocation, osteoarthritis or arthritis of the knee and any abnormal knee radiographs, joint infection, injury, Osgood-Schlatter patients or any pathological patients

Intervention groups
In the intervention group, real acupuncture sessions were performed, three sessions per week for two consecutive weeks, while sham acupuncture sessions were performed in the non-intervention group.

Main outcome variables
Pain, activities of daily living, quality of life, functional tests

General information

Reason for update

Acronym
EAPFP

IRCT registration information
IRCT registration number: **IRCT20241118063761N1**
Registration date: **2024-12-10, 1403/09/20**
Registration timing: **prospective**

Last update: **2024-12-10, 1403/09/20**
Update count: **0**

Registration date
2024-12-10, 1403/09/20

Registrant information

Name
Mehdi Jafari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 919 664 8470

Email address
jafarimohammadmehdi35@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-23, 1403/10/03

Expected recruitment end date
2025-03-23, 1404/01/03

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of acupuncture on pain and function in patients with patellofemoral pain syndrome: a clinical trial study

Public title

Investigating the effect of acupuncture on pain and function in patients with patellofemoral pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 to 35 years Diagnosis of unilateral patellofemoral syndrome based on at least 5 of the 7 listed symptoms (pain elicited by at least two of the following four tests: (i) isometric muscle contraction with slight knee flexion, (ii) patellofemoral joint line palpation, (iii) patellar compression against the femur (IV) active resisted knee extension.)There is no evidence of other intra- or extra-articular knee injuries as determined by physical examination and radiographic evaluation intensity of 3 on the VAS scale, No history of knee trauma Intra-articular injection or physiotherapy within the last 3 months or surgery No use of non-steroidal anti-inflammatory drugs within 15 days prior to treatment Full cooperation with the study

Exclusion criteria:

Age outside the range of 18 to 35 years Diagnosis of Patellofemoral Pain Syndrome based on 5 or fewer out of 7 listed symptoms Presence of other intra-articular or extra-articular knee injuries Pain intensity less than 3 on the VAS scale History of knee injury, intra-articular injection, physiotherapy in the past 3 months, or surgery Use of non-steroidal anti-inflammatory drugs within 15 days prior to the start of treatment Lack of full cooperation with the study

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method will be used, using a random number table or random number generator, to randomly assign patients to two groups. Instead of patient names and identification, we will use random codes. The researchers will only see the codes and will remain unaware of the patients' true identities.

Blinding (investigator's opinion)

Double blinded

Blinding description

The use of sealed envelopes to randomly assign individuals to study and control groups prevents both the researcher and the participant from knowing which group they are assigned to

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1134845764

Approval date

2024-05-21, 1403/03/01

Ethics committee reference number

IR.IUMS.FMD.REC.1403.142

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

Pain

Timepoint

Immediately, one and three months after the intervention

Method of measurement

Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Score of Knee Injury and Osteoarthritis Outcome Score (KOOS)
Timepoint
Immediately after the intervention, one and three months after the intervention
Method of measurement
Knee Injury and Osteoarthritis Outcome Score (KOOS)

2

Description
Measuring time climbing stairs
Timepoint
Immediately after the intervention, one and three months after the intervention
Method of measurement
Digital Stopwatch

3

Description
Ṡingle leg hop test
Timepoint
Immediately after the intervention, one and three months after the intervention
Method of measurement
Tape meter

Intervention groups

1

Description
Intervention group: Nine acupuncture sessions, three sessions per week, one day in between
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Akram educational, Research and treatment complex
Full name of responsible person
Mohammadmehdi Jafari
Street address
Hospital of Hazrat Rasool Akram,Corner of Mansouri Street, Starkhan-Kh.Niyaish, Tehran
City
tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 8670 5503
Email
dr_m.mahdi1992@yahoo.com
Web page address
https://hrmc.iums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Iran University of Medical Sciences, Research Deputy, Central Headquarters (fifth floor),Hemat Highway between Sheikh Fadlallah and Chamran Expressway.
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 8670 5503
Fax
Email
falak.r@iums.ac.ir
Web page address
https://hrmc.iums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mohammad Mahdi Jafari
Position
Student
Latest degree

Medical doctor

Other areas of specialty/work
Sport Medicine

Street address
Sports medicine department, Hazrat Rasoul Akram hospital complex, Niayesh St, Sattarkhan St

City
Tehran

Province
Tehran

Postal code
14455613131

Phone
+98 21 6435 2446

Fax
+98 21 6651 7309

Email
jafarimohammadmehdi35@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Mahdi Jafari

Position
Student

Latest degree
Medical doctor

Other areas of specialty/work
Sport Medicine

Street address
Sports medicine department, Hazrat Rasoul Akram hospital complex, Niayesh St, Sattarkhan St

City
Tehran

Province
Tehran

Postal code
14455613131

Phone
+98 21 6435 2446

Fax
+98 21 6651 7309

Email
jafarimohammadmehdi35@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Mohammad Mahdi Jafari

Position
Student

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Sport Medicine

Street address
Sports medicine department, Hazrat Rasoul Akram hospital complex, Niayesh St, Sattarkhan St

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Tehran

Province
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14455613131

Phone
+98 21 6435 2446

Fax
+98 21 6651 7309

Email
jafarimohammadmehdi35@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
No more information available.

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Not applicable

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available