Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the clinical and immunological effectiveness of laser acupuncture, manual acupuncture, and sham in the treatment of knee osteoarthritis

Protocol summary

Study aim

Comparison of clinical and immunological effectiveness of laser acupuncture versus manual acupuncture and routine drug treatment in patients with knee osteoarthritis referred to the rheumatology clinic of Ghaem Hospital

Design

This is a Phase 2, randomized, single-blind, parallel-group, controlled clinical trial involving 90 patients. Randomization will be performed using blocks of six, with the allocation sequence generated via the Sealed Envelope website. The process involves 16 blocks of six—each containing two instances of letters A, B, and C—assigned to numbers 1 through 90. The letters will be placed inside opaque envelopes corresponding to these numbers; the envelope will be sealed with the number written on the outside. Participants will select envelopes sequentially, starting with number 1, and will be assigned to the corresponding group upon opening the envelope, thereby ensuring equal distribution across the three groups.

Settings and conduct

After reviewing the inclusion criteria and filling out the informed consent form, patients are referred by a rheumatologist from the Rheumatology Clinic of Ghaem Hospital to the Acupuncture Clinic of Imam Reza Hospital in Mashhad and are randomly assigned to one of the three study groups. Blinding is fully described in the relevant section.

Participants/Inclusion and exclusion criteria

Patients 45 years and older Having the diagnostic criteria of the American College of Rheumatology Complaint of knee pain for more than 3 months Last 6 months radiology: Grade 2 or 3 Kellogg Lawrence Medial tibiofemoral osteoarthritis more than lateral in at least one knee NSR 4 or more Not taking omega-3 and glucosamine during the study Not having undergone physical therapy in the past three months No other concomitant rheumatic disease Willingness to sign informed consent

Intervention groups

Manual acupuncture, laser acupuncture, laser sham control

Main outcome variables

Pain, knee joint function and stiffness, blood levels of immunological factors, quality of life, need for painkillers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110809007265N15**
Registration date: **2025-11-01, 1404/08/10**
Registration timing: **prospective**

Last update: **2026-09-14, 1405/06/23**
Update count: **1**

Registration date

2025-11-01, 1404/08/10

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1855 2188

Email address

azizih@mums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date
2025-12-22, 1404/10/01
Expected recruitment end date
2027-03-21, 1406/01/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the clinical and immunological effectiveness of laser acupuncture, manual acupuncture, and sham in the treatment of knee osteoarthritis

Public title
Comparison of laser and manual acupuncture in knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 45 and above Patients with the diagnostic criteria of the American College of Rheumatology Complaint of knee pain for more than 3 months Radiological examination in the last 6 months indicating grade 2 or 3 of Kellgren lawrence with interpretation and confirmation by a respected rheumatologist Patients with medial tibiofemoral osteoarthritis in at least one knee A score of 4 or higher on the NSR Do not consume omega-3 and glucosamine while studying Not undergoing physiotherapy in the past three months At the same time, they should not have another rheumatic disease such as rheumatoid arthritis
Exclusion criteria:
Previous knee surgery on the knee being evaluated or pending any surgery for both knees Knee pain caused by other pathologies (such as meniscus tear, rheumatoid arthritis, joint space infection, malignancy, gout, lumbosacral diseases with lower limb symptoms, etc.) A history of arthroscopy within the last year or a history of intra-articular injection within the last 6 months for knee evaluation Each of the knees has received acupuncture/physical therapy in the past 6 months Severe acute or chronic organic or neuropsychiatric disorder Coagulation disorders (such as hemophilia) Autoimmune disorders Malignancies Patients with epilepsy or those with a pacemaker Drug use Physiotherapy a month ago Preparation for pregnancy, pregnancy or breastfeeding period Patients who have participated in other acupuncture clinical studies in the past month
Age
From **45 years** old
Gender
Both

Phase
3
Groups that have been masked
- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
In the random allocation, we will use blocks of 6 and use the sealedenvelope website. In this type of allocation, 16 blocks of 6 are generated by the system (2 of each letter) and are numbered from 1 to 90. The letters are placed in the order of their numbers in a matte envelope, the number is written on the envelope, and the lid is closed. People start taking the envelope in the order of their arrival from envelope number 1, open it, and are referred to the relevant group. In this way, people are placed equally in three groups. After the blocks are determined, they are placed in envelopes that cannot be seen from the outside, the letters are placed in them, and a number is written in order. People take the envelope in the order of their arrival and are assigned to the relevant group.
Blinding (investigator's opinion)
Single blinded
Blinding description
All patients who enter the study first fill out an informed consent form, which states that the patient will be randomly assigned to one of three study groups: manual acupuncture, laser acupuncture, and the control group. Given that sham laser acupuncture is performed in the control group, patients in the laser acupuncture and control groups will be blinded to receiving the laser acupuncture intervention but will be aware that they will not receive conventional acupuncture. Patients in the manual acupuncture group will also likely notice the difference between this method and laser acupuncture, so blinding can only be done partially for the laser acupuncture and sham laser acupuncture groups. Blinding of the acupuncture specialist (principal investigator) is not possible. The referring rheumatologist, the nurse who takes the blood sample, the immunologist and expert, and the statistician will be responsible for collecting data and evaluating the outcomes for the assigned group of patients. The acupuncture resident responsible for data collection and overall patient follow-up will also be blinded to the assigned patient group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Mashhad University of Medical Sciences

Street address
Shahid Fakouri Blvd., between Shahid Javan Sq. and Al Shahidi Sq., Mashhad, Khorasan Razavi Province

City
Mashhad

Province
Razavi Khorasan

Postal code
9177899191

Approval date
2025-06-21, 1404/03/31

Ethics committee reference number
IR.MUMS.REC.1404.154

Health conditions studied

1

Description of health condition studied
Gonarthrosis [arthrosis of knee]

ICD-10 code
M17

ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Pain

Timepoint
The trial duration is 16 weeks, including 8 weeks of treatment and 8 weeks of follow-up.

Method of measurement
Pain based on Visual Analogue Scale

2

Description
Knee joint performance status

Timepoint
Before treatment, week 4, week 8, and week 16

Method of measurement
Based on Western Ontario and McMaster Universities Arthritis Index (WOMAC)

3

Description
Knee stiffness

Timepoint
Before treatment, week 4, week 8, and week 16

Method of measurement
Based on Western Ontario and McMaster Universities Arthritis Index (WOMAC)

4

Description
Blood level of immunologic factors VEGF IL23 IL17

Timepoint
Before studying and week 8

Method of measurement
Blood samples from patients will be taken for immunological tests before the study and at week 8. The blood samples will be stored at -80 degrees in the reference lab so they can be used for future studies as well.

Secondary outcomes

1

Description
Quality of life

Timepoint
Before treatment, week 4, week 8, and week 16

Method of measurement
Based on Short Form (36) Health Survey (SF 36)

2

Description
The need for using painkillers

Timepoint
Before treatment, week 4, week 8, and week 16

Method of measurement
Based on the patient's medical history as well as the form listing the painkillers used by the patient

3

Description
Side effects

Timepoint
Week 4, week 8, and week 16

Method of measurement
Based on the patient's medical history as well as the form about side effects filled out by the patient

Intervention groups

1

Description
First Intervention group: Manual acupuncture twice a week for 8 weeks

Category
Treatment - Devices

2

Description
Second Intervention group: Laser acupuncture twice a week for 8 weeks

Category
Treatment - Devices

3

Description
Control group: Sham laser twice a week for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Acupuncture clinic of Imam Reza Hospital, Mashhad, Iran
Full name of responsible person
Dr Hoda Azizi
Street address
Shahid Fakouri Blvd., between Shahid Javan Sq. and Al Shahidi Sq., Mashhad, Khorasan Razavi Province
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3879 5031
Email
presidentoffice@mums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Hoda Azizi
Street address
Shahid Fakouri Blvd., between Shahid Javan Sq. and Al Shahidi Sq., Mashhad, Khorasan Razavi Province
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3879 5031
Email
presidentoffice@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Dr Hoda Azizi
Position
Associate profesor
Latest degree
Ph.D.
Other areas of specialty/work
Acupuncture and Chinese medicine
Street address
Shahid Fakouri Blvd., between Shahid Javan Sq. and Al Shahidi Sq., Mashhad, Khorasan Razavi Province
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3879 5031
Email
AziziH@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr Hoda Azizi
Position
Associate profesor
Latest degree
Ph.D.
Other areas of specialty/work
Acupuncture and Chinese medicine
Street address
Shahid Fakouri Blvd., between Shahid Javan Sq. and Al Shahidi Sq., Mashhad, Khorasan Razavi Province
City
Mashhad
Province
Razavi Khorasan

Postal code
9177899191
Phone
+98 51 3879 5031
Email
AziziH@mums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Taha Sharafian
Position
resident of acupunture
Latest degree
Medical doctor
Other areas of specialty/work
acupuncture and Chinese medicine
Street address
Shahid Fakouri Blvd., between Shahid Javan Sq. and Al Shahidi Sq., Mashhad, Khorasan Razavi Province
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 51 3879 5031
Email
sharafianT4011@mums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available