Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Study and comparison of the effectiveness of high-intensity laser and intra-articular laser treatment followed by ultrasound-guided platelet-rich plasma (PRP) injection on improving symptoms in patients with knee osteoarthritis

Protocol summary

Study aim

The aim of this study was to compare the effectiveness of high-intensity laser and intra-articular laser followed by ultrasound-guided platelet-rich plasma injection in reducing pain, improving function, and satisfaction with treatment in patients with knee osteoarthritis.

Design

A controlled, parallel-group, single-blind, randomized, phase 3 clinical trial on 40 patients. Randomization software is used for randomization.

Settings and conduct

Using a sealed envelope, the outcome assessor and data analyst will be blinded to the treatment group, and the patients will be randomly divided into 2 groups of 20. The study site will be Shahid Modarres Hospital, Tehran.

Participants/Inclusion and exclusion criteria

Individuals aged 40 to 70 years with a BMI between 18 and 30 who were diagnosed with knee osteoarthritis based on history and physical examination and confirmed by knee radiography (Kellgren–Lawrence grade 2-3) and had symptoms lasting more than 3 months. Exclusion criteria included: history of uncontrolled diabetes, immunodeficiency, and collagen disorders ;use of NSAIDs within 2 days prior to injection; pregnancy or lactation; genu valgum/varum greater than 20 degrees; clinical or paraclinical signs in favor of spinal canal narrowing, neuropathy, or active lumbar radiculopathy.

Intervention groups

Intervention group 1: Includes 20 patients who undergo three PRP injections every two weeks and then 10 sessions of high-intensity laser treatment twice a week.
Intervention group 2: Includes 20 patients who undergo three PRP injections every two weeks and then 3 sessions of intra-articular laser treatment immediately after each PRP treatment.

Main outcome variables

Assessing the level of pain and stiffness in the knee joint, assessing the patient's performance in performing daily tasks, and the level of satisfaction with treatment.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N38**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-22, 1405/02/02**
Update count: **0**

Registration date

2026-04-22, 1405/02/02

Registrant information

Name
Seyed Ahmad Raeissadat
Name of organization / entity
Modares Hospital
Country
Iran (Islamic Republic of)
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Email address
a_raeissadat@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-11-26, 1404/09/05

Expected recruitment end date
2026-09-27, 1405/07/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study and comparison of the effectiveness of high-intensity laser and intra-articular laser treatment followed by ultrasound-guided platelet-rich plasma (PRP) injection on improving symptoms in patients with knee osteoarthritis

Public title
Study and comparison of the effectiveness of high-intensity laser and intra-articular laser treatment followed by ultrasound-guided platelet-rich plasma (PRP) injection on improving symptoms in patients with knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals aged 40 to 70 years who are diagnosed with knee osteoarthritis based on history and physical examination. Duration of symptoms is more than 3 months. Diagnosis is confirmed using knee radiography (Kellgren–Lawrence grade 2-3). Patient's BMI is between 18 and 30. Patient's willingness to participate in the study
Exclusion criteria:
History of immunodeficiency and collagen disorders and uncontrolled diabetes History or presence of malignant disorders, infection or active ulcer in the knee area Recent history of severe knee injury Autoimmune and platelet disorders Treatment with anticoagulant and antiplatelet drugs within 10 days prior to injection Use of NSAIDs within 2 days prior to injection History of intramuscular injection or oral administration of systemic corticosteroids 2 weeks prior to injection History of any intra-articular knee injection within the past 6 months Hemoglobin less than 11 g/dL Platelet count less than 150,000/mL History of vasovagal shock Pregnancy or breastfeeding Genu valgum/varum greater than 20 degrees Hemarthrosis, erythema, and psoriatic lesions Clinical or paraclinical signs in favor of spinal canal stenosis, neuropathy, or active lumbar radiculopathy
Age
From **40 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In this clinical trial, 40 patients diagnosed with knee osteoarthritis will be randomly enrolled in the study. Block Randomization will be used to randomly assign individuals to the study groups. In this method, blocks of 4 will be used with a 1:1 ratio. Random Allocation software will be used to generate random sequences. Random Allocation software will be used to generate random sequences. The random sequences generated in this method, which are identified by the letters A (group receiving high-intensity laser followed by PRP) and B (group receiving intra-articular laser followed by PRP), will be recorded on cards and these cards will be placed in sealed envelopes in order.Finally, the numbered envelopes will be placed in a folder. Then, based on the order of entry of the eligible participants, the envelopes will be opened and the assigned group of that participant will be determined.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, due to the nature of the study, it was not possible to blind the patient and the researcher. Only the data analyst will be kept blind and will not be informed of the intervention performed on each group of patients. Only the final data in the form of the first and second groups of random numbers assigned to each patient will be made available to them.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University of Medical Sciences
Street address
Tehran, Shahid Chamran Highway, Yemen Street, next to Taleghani Hospital, Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2025-11-22, 1404/09/01
Ethics committee reference number

IR.SBMU.MSP.REC.1404.538

Health conditions studied

1

Description of health condition studied
Knee osteoarthritis
ICD-10 code
M17
ICD-10 code description
Osteoarthritis of knee

Primary outcomes

1

Description
Assessment of knee pain
Timepoint
At the beginning of the study (before the intervention) and 4 weeks and 24 weeks after the intervention
Method of measurement
Based on the visual pain index, WOMAC questionnaire, and Lequesne index

2

Description
Assessing the patient's performance in performing daily tasks
Timepoint
At the beginning of the study (before the intervention) and 4 weeks and 24 weeks after the intervention
Method of measurement
Using the WOMAC questionnaire

3

Description
Assessing morning dryness
Timepoint
At the beginning of the study (before the intervention) and 4 weeks and 24 weeks after the intervention
Method of measurement
Using the WOMAC questionnaire and Lequesne index

Secondary outcomes

1

Description
Patient satisfaction with treatment
Timepoint
At the beginning of the study (before the intervention) and 4 weeks and 24 weeks after the intervention
Method of measurement
5-choice questionnaire

Intervention groups

1

Description
Intervention group: Includes 20 patients who undergo intra-articular injection of 5 cc PRP in three injections at two-week intervals along with 10 high-intensity laser sessions, two sessions per week.
Category
Treatment - Other

2

Description
Intervention group: Includes 20 patients who undergo intra-articular injection of 5 cc PRP in three injections at two-week intervals, along with 3 intra-articular laser sessions immediately after each PRP session.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Modares Hospital
Full name of responsible person
Seyyed Ahmed RaeisSadat
Street address
Saadat Abad, intersection of Saadat Abad and Yadgar Imam, Shahid Modarres Hospital
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Sponsors / Funding sources

1

Sponsor
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad eyed abusaeedi
Position
Consultant of Physical Medicine and Rehabilitation
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Person responsible for updating data

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s.mohammadabusaeedi@gmail.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
Undecided - It is not yet known if there will be 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
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
Title and more details about the data/document
All data from study participants can be shared after de-

identifying individuals.

When the data will become available and for how long

Access period begins one year after results are published.

To whom data/document is available

The data from this study will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

If the researchers' goal is to conduct a systematic review and meta-analysis of the data, non-identifiable patient data will be made available to the researchers.

From where data/document is obtainable

By sending an email to s.mohammadabusaeedi@gmail.com

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

The request must include information about the applicant, their place of work, phone number, email, and the reason for their request. If these items are provided and the applicant's plan information is registered and approved in the PROSPERO system, the information will be made available to the applicant.

Comments