Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Effects of Intra-Articular Corticosteroid Injection and Intra-Articular Laser Therapy in Patients with Knee Osteoarthritis

Protocol summary

Study aim
To compare the efficacy of single dose intraarticular corticosteroid injection and intraarticular low level laser therapy in knee osteoarthritis in terms of pain, osteoarthritis outcomes, quality of life, and adverse events.

Design
A phase II, randomized, controlled, parallel group, double blind clinical trial involving 54 patients. Block randomization with a block size of 6 will be performed using Random Allocation Software.

Settings and conduct
This clinical trial will be conducted at the Physical Medicine and Rehabilitation Clinic of Firoozgar Hospital, Tehran. Patients will receive either intraarticular injection of 40 mg triamcinolone or intraarticular laser therapy. Procedures will be ultrasound guided, with participant and outcome assessor blinding.

Participants/Inclusion and exclusion criteria
Patients aged 45 to 75 years with knee osteoarthritis diagnosed by ACR clinical and radiographic criteria, Kellgren Lawrence grade 2 or 3, and a pain score of at least 4 of 10 will be included. Major exclusions include recent joint injection, surgery or planned arthroplasty, inflammatory or secondary arthritis, bleeding risk, infection, malignancy, diabetes, pregnancy, breastfeeding, relevant medication use, or hypersensitivity. Withdrawal includes withdrawal of consent, new exclusion criteria, loss to follow up, serious adverse events, nonadherence, or protocol violation.

Intervention groups
Group A receives ultrasound guided intraarticular triamcinolone acetonide, 40 mg in 1 mL, plus sham laser. Group B receives intraarticular laser therapy, 658 nm, 50 mW, for 20 minutes, delivering 60 J, plus sham injection of 0.5 mL normal saline.

Main outcome variables
Pain will be assessed by the Visual Analogue Scale (VAS) and function by the validated Persian Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) at baseline, week 1, and month 1. Adverse events will be recorded.

General information

Reason for update

Acronym
IALT

IRCT registration information
IRCT registration number: **IRCT20190306042945N8**
Registration date: **2026-09-29, 1405/07/07**
Registration timing: **registered_while_recruiting**

Last update: **2026-09-29, 1405/07/07**
Update count: **0**

Registration date
2026-09-29, 1405/07/07

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-06, 1405/06/15

Expected recruitment end date
2027-01-05, 1405/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Intra-Articular Corticosteroid Injection and Intra-Articular Laser Therapy in Patients with Knee Osteoarthritis

Public title
Comparison of Intra-Articular Corticosteroid Injection and Intra-Articular Laser Therapy for the Treatment of Knee Osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age between 45 and 75 years Diagnosis of knee osteoarthritis based on the American College of Rheumatology (ACR) clinical and radiographic criteria Kellgren–Lawrence grade 2 or 3 knee osteoarthritis (mild-to-moderate OA) Knee pain score of ≥4 out of 10 on the Visual Analogue Scale (VAS) Willingness to participate in the study and provision of written informed consent
Exclusion criteria:
History of intra-articular injection within the past 3 months, including corticosteroids, hyaluronic acid, platelet-rich plasma (PRP), or other injectates History of major knee surgery or planned total or partial knee arthroplasty Diagnosis of inflammatory arthritis, such as rheumatoid arthritis, gout, or psoriatic arthritis Secondary causes of osteoarthritis, such as post-traumatic osteoarthritis Coagulation disorders or current use of anticoagulant therapy Active infection Malignancy Diabetes mellitus Concurrent use of systemic corticosteroids Pregnancy or breastfeeding Known hypersensitivity to corticosteroids or laser-therapy–related components Use of oral nonsteroidal anti-inflammatory drugs (NSAIDs) or systemic corticosteroids within the past 7 days
Age
From **45 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be allocated to one of two treatment groups using block randomization with a block size of 6: Group 1: Intra-articular corticosteroid injection Group 2: Intra-articular laser therapy (IALT) For randomization, a set of small papers of identical size, color, and material will be prepared. Each paper will be labeled with a number indicating the treatment group (number 1 for corticosteroid injection and number 2 for laser therapy). Based on a sample size of 54 participants, nine complete blocks, each containing 6 participants, will be designed. Within each complete block, three allocations will be assigned to Group 1 and three allocations to Group 2. The sequence of group assignments within each block will be generated completely at random using Random Allocation Software.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is designed as a double-blind trial; both the participants and the personnel responsible for completing the questionnaires will be unaware of treatment-group allocation. However, given the practical and ethical limitations arising from the inherent differences between the interventions (drug versus energy), complete blinding of the interventionist is not feasible in this protocol. Therefore, the primary focus will be on maintaining blinding of participants and outcome assessors. Group A (Corticosteroid): Participants will receive an ultrasound-guided intra-articular injection of 40 mg triamcinolone acetonide. To simulate the laser procedure, an inactive optical fiber with a visible red indicator light will be introduced through the same needle, without delivery of therapeutic energy. Group B (Laser therapy): Participants will receive intra-articular laser therapy using a 658-nm wavelength (red light) at a power of 50 mW for 20 minutes (total energy: 60 J), delivered through a sterile optical fiber inserted using a 22-gauge needle. To simulate drug injection, 0.5 mL of normal saline will be injected and subsequently aspirated/reinjected to reproduce the physical sensation of an injection. To assess the success of blinding, participants and outcome assessors will periodically be asked to guess the assigned treatment group. These data will be recorded and evaluated in sensitivity analyses to assess the potential impact of lack of interventionist blinding on the study results.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee, School of Medicine, Iran University of Medical Sciences
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Vice-Chancellery for Research and Technology, Central Headquarters Building, Iran University of Medical Sciences, adjacent to Milad Tower, Hemmat

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Approval date
2026-03-14, 1404/12/23

Ethics committee reference number
IR.IUMS.FMD.REC.1404.771

Health conditions studied

1

Description of health condition studied
Knee Osteoarthritis

ICD-10 code
M17.10

ICD-10 code description
Unilateral primary osteoarthritis, unspecified knee

Primary outcomes

1

Description
Pain score

Timepoint
Before the intervention,7 days and 30 days after the intraarticular injection.

Method of measurement
Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group :Participants receive intra-articular low-level laser therapy with a wavelength of 658 nm (red light), output power of 50 mW, for 20 minutes (total energy of 60 J) in a single session. The procedure is performed under ultrasound guidance using a sterile optical fiber introduced via a 22-gauge needle into the knee joint space. For blinding and simulating drug injection, 0.5 mL of normal saline is injected and re-aspirated to reproduce the physical sensation of injection.

Category
Treatment - Devices

2

Description
Control group: Participants receive 40 mg (1 mL) of triamcinolone acetonide injectable suspension intra articularly under ultrasound guidance in a single session. For blinding and simulating the laser procedure, an inactive optical fiber with a red guide light (delivering no therapeutic energy) is inserted through the same needle into the joint space for 20 minutes.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Firoozgar Hospital

Full name of responsible person
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Sponsors / Funding sources

1

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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
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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
All data is shareable, provided it has been fully de-identified.
When the data will become available and for how long
Access will be available starting 6 months after the publication of the results.
To whom data/document is available
Access is restricted to researchers affiliated with academic and scientific institutions.
Under which criteria data/document could be used
For future research use, please submit a written request via email.
From where data/document is obtainable
Principal Investigator: Dr. Bijan Forogh Email: forogh.b@iums.ac.ir

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

Upon submission of your request, data access will be provided within approximately one week.

Comments