Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the short-term efficacy of intra-articular platelet-rich plasma injection alone versus intra-articular platelet-rich plasma injection combined with high-power laser therapy on pain and physical function in patients with grade 1-3 knee osteoarthritis

Protocol summary

Study aim
Comparison of short-term efficacy of intra-articular PRP alone vs PRP combined with HILT in knee OA (grades 1-3).

Design
Randomized controlled trial, parallel group, single-blind (patient-blinded), 48 patients (24 per group), block randomization (4 blocks of 12) using random number software, allocation concealment with sequentially numbered sealed opaque envelopes.

Settings and conduct
Patients at Imam Khomeini Hospital's physical medicine clinic (Tehran) were split into two groups of 24. Group 1 received one PRP injection; Group 2 received the injection plus high-intensity laser. Assessments (VAS and Persian WOMAC) were done before, 1 month, and 3 months post-injection. The laser operator was unblinded (single-blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: 30-70y; knee OA grade 1-3 (ACR criteria); pain≥6 months; VAS≥3; failed conservative Tx; washout≥2 weeks for NSAIDs/cortisone; no injection in last 3 months. Exclusion criteria: pregnancy; inflammatory arthritis; severe heart disease; skin infection; immunosuppressants/anticoagulants; bleeding disorders; active radicular low back pain; knee surgery in last 3 months; active infection/malignancy in last 6 months; substance abuse; intra-articular corticosteroid (3 months) or hyaluronic acid (6 months). Controlled diabetes allowed.

Intervention groups
Group 1 (PRP alone): Single intra-articular PRP injection (4 mL, platelet concentration 5-6 times baseline, prepared by double centrifugation of 20 mL whole blood with anticoagulant). Group 2 (PRP+HILT): Single PRP injection (same protocol) followed by one session of HILT (pulsed mode, max power 12W, average 7W, dose 50 J/cm² per 64 cm², frequency 10 Hz, duration 6 minutes).

Main outcome variables
Pain severity (Visual Analogue Scale - VAS); Pain subscale of WOMAC; Stiffness subscale of WOMAC; Physical function subscale of WOMAC.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260420069117N1**
Registration date: **2026-05-20, 1405/02/30**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-20, 1405/02/30**
Update count: **0**

Registration date
2026-05-20, 1405/02/30

Registrant information

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Recruitment status
recruiting

Funding source

Expected recruitment start date

2026-04-30, 1405/02/10

Expected recruitment end date

2027-03-20, 1405/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the short-term efficacy of intra-articular platelet-rich plasma injection alone versus intra-articular platelet-rich plasma injection combined with high-power laser therapy on pain and physical function in patients with grade 1-3 knee osteoarthritis

Public title

Comparison of PRP injection with or without high-power laser for knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 30 and 70 years Diagnosis of knee osteoarthritis grade 1, 2 or 3 based on ACR clinical and radiographic criteria Knee pain for at least 6 months Visual Analogue Scale (VAS) score of at least 3 No satisfactory response to at least one conservative treatment (acetaminophen, NSAIDs, assistive devices, lifestyle modification or weight loss) At least two weeks washout period from last NSAID or corticosteroid use No history of knee injection in the last three months

Exclusion criteria:

Pregnancy or breastfeeding Inflammatory rheumatic diseases Severe heart disease Active skin infection at the injection site Use of immunosuppressive drugs Use of anticoagulants (warfarin or heparin) History of bleeding diathesis or current coagulation disorders Active low back pain with radiation to lower limbs History of knee surgery in the last 3 months Active infection or malignancy in the last 6 months Substance abuse Intra-articular corticosteroid injection in the last 3 months Intra-articular hyaluronic acid injection in the last 6 months

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Method: Block randomization (restricted randomization) with fixed block size of 12. Four blocks will be used, each containing 6 allocations to PRP alone group and 6 allocations to PRP+HILT group. Unit of randomization: Individual patient. Tools: Random number generation using R software to randomly select 4 numbers from 1 to 4 for block order. Allocation concealment using sequentially numbered, sealed, opaque envelopes. Each random sequence is recorded on a card placed inside an envelope. Envelopes are numbered externally in sequence and opened in order of participant enrollment.

Blinding (investigator's opinion)

Single blinded

Blinding description

This is a single-blind (patient-blinded) study. The blinding is achieved as follows: Participants (patients): Blinded. For patients in the PRP-only group (Group 1), a sham laser procedure is performed with the same device, same duration (6 minutes), same positioning and sound effects, but with zero watt power output. Patients in the PRP+HILT group (Group 2) receive real laser therapy. All patients are unaware of their group allocation. Principal investigator: Not blinded. The investigator knows which patient receives which intervention. Healthcare providers (interventionists/laser operator): Not blinded. The laser operator must know the actual power settings to deliver real or sham laser accordingly. Data collectors: Not applicable separately, as outcome assessors are described below. Outcome assessors: Blinded. The physician or trained personnel who administer the VAS and WOMAC questionnaires at baseline, 1 month and 3 months follow-up are unaware of the patients' group allocation. Assessments are performed before laser session (for Group 2) and at the same time points for both groups. Data Safety and Monitoring Board (DSMB): Not applicable (no DSMB for this trial). Manuscript writers: Not blinded during analysis; however, group allocation will be coded (e.g., Group A and Group B) until final analysis is completed.

Placebo

Used

Assignment

Parallel

Other design features

No applicable

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Imam Khomini Hospital Educational, Research and Treatment Center - Tehr

Street address

End of Keshavarz Boulevard

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2026-04-20, 1405/01/31

Ethics committee reference number

IR.TUMS.IKHC.REC.1405.037

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis (Knee OA) is a chronic degenerative joint disease characterized by progressive destruction of articular cartilage, synovial inflammation, and subchondral bone changes. It leads to persistent pain, stiffness, and functional disability. This study specifically includes patients with grade 1, 2, or 3 knee osteoarthritis based on radiographic criteria (Kellgren-Lawrence classification).

ICD-10 code

M17.9

ICD-10 code description

Osteoarthritis of knee, unspecified

Primary outcomes

1

Description

Pain severity measured by Visual Analogue Scale (VAS). The VAS is a 10-centimeter horizontal line with 0 meaning "no pain" and 10 meaning "worst imaginable pain". Patients mark their current pain level on this line.

Timepoint

Before injection (baseline), 1 month after injection, 3 months after injection

Method of measurement

Visual Analogue Scale (VAS) - a self-administered 10-centimeter horizontal line scale. The patient places a mark on the line corresponding to their perceived pain intensity. The distance from zero to the mark is measured in millimeters, yielding a score from 0 to 100 (or 0 to 10 when converted).

Secondary outcomes

1

Description

Physical function measured by the physical function subscale of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). This subscale contains 17 questions assessing difficulty with daily activities such as walking, climbing stairs, rising from sitting, standing, bending, and household tasks.

Timepoint

Before injection (baseline), 1 month after injection, 3 months after injection

Method of measurement

Persian version of the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) physical function subscale. Each of the 17 questions is scored from 0 (no difficulty) to 4 (extreme difficulty). The total subscale score ranges from 0 to 68. Higher scores indicate worse physical function.

Intervention groups

1

Description

Control group: Platelet-rich plasma (PRP) injection alone. Preparation method: 20 mL of venous blood is drawn with 3 mL of anticoagulant (citrate dextrose solution A or acid citrate dextrose), divided equally into 4 tubes. Double centrifugation method: first centrifugation at 1800 rpm for 15 minutes, plasma is transferred to a new tube, second centrifugation at 1800 rpm for 12 minutes. Final product is 4 mL of PRP with platelet concentration 5 to 6 times baseline (approximately 1-1.5 million platelets per microliter). A single intra-articular injection of 4 mL PRP is administered to the affected knee under sterile conditions. No further intervention is given. Sham laser (0 watt) is applied for 6 minutes with the same device appearance and duration to maintain blinding. Manufacturer of centrifuge and PRP preparation kit: to be specified based on hospital procurement.

Category

Treatment - Drugs

2

Description

Intervention group: Platelet-rich plasma (PRP) injection followed by high-intensity laser therapy (HILT). PRP preparation and injection protocol is identical to Intervention group 1 (4 mL PRP, single intra-articular injection, platelet concentration 5-6 times baseline). One to two weeks after PRP injection, a single session of HILT is performed. Laser parameters: pulsed mode, maximum power 12 watts, average power 7 watts, dose 50 Joules per square centimeter applied to each 64 square centimeters of the anterior knee area, frequency 10 Hertz, total duration 6 minutes. Laser device: High-intensity laser therapy system (specific manufacturer and model to be specified based on hospital equipment, e.g., ASA Laser or similar class 4 laser device). No sham procedure is applied to this group.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Zahra Emami Razavi

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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?
No
Title of funding source
Tehran 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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
After deidentifying people, all the data obtained from the research, including the demographic information of the samples, clinical information and the results of the intervention can be shared.
When the data will become available and for how long
It is possible to access the results after nine to twelve months from the publication of the results.
To whom data/document is available
Researchers in academic centers and scientific research centers.
Under which criteria data/document could be used
In order to data comparison in similar studies, the researchers of academic centers and scientific research centers have the possibility to receive data and re-analyze it if they comply with the principles of ethics in research.
From where data/document is obtainable
Dr Alireza naeiji with below email address: alirezanaeiji3@gmail.com and phone number:+989116899200
What processes are involved for a request to access data/document
Researchers should send a written request to receive data to the relevant email address.A week after receiving an email , it will take action.
Comments