Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effects of intra-articular injection of platelet-rich plasma (PRP) on pain and function of patients with knee osteoarthritis and comparison of the efficacy between moderate and severe degrees of knee osteoarthritis based on the Kellgren Lawrence classification

Protocol summary

Study aim

Assessing the impact of intra-articular platelet-rich plasma (PRP) injections on pain and function in knee osteoarthritis. Comparing the efficacy of PRP injections between moderate and severe knee osteoarthritis. Developing evidence-based PRP injection protocols for moderate and severe knee osteoarthritis

Design

The number of participants in this study, based on statistical formulas, is 82 volunteers, including 41 people with moderate disease severity (Kellgren-Lawrence grade 2 and 3) and 41 people with severe disease (Kellgren-Lawrence grade 4).

Settings and conduct

Patients with knee pain who refer to the sports medicine clinic of Imam Khomeini Hospital and have been diagnosed with osteoarthritis, have at least grade 2 osteoarthritis on standing knee radiographs, and have not responded to supportive treatments for at least three months are selected for this study. After obtaining consent to participate in this study, individuals will undergo two injections of PRP 2-4 weeks apart.Assessments include a VAS scale and WOMAC questionnaire, which are completed at the initial visit and two and six months after the second injection. The 30s Chair Stand Test (30sCST) and 40m Fast-Paced Walk Test (40mFPWT) are also assessed before the injection and two months after the second injection.

Participants/Inclusion and exclusion criteria

Patients with knee pain at the sportsmedicine clinic of Imam Khomeini Hospital and have been diagnosed with osteoarthritis, have at least grade 2 osteoarthritis on standing knee radiographs, and not responded to supportive treatments for at least three months are selected for the study.

Intervention groups

Individuals will receive the injection After consentement.The second injection will be done two to four weeks after the first injection

Main outcome variables

VAS; WOMAC questionnaire; 30CST; 40mFPWT

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250305064943N1**
Registration date: **2025-05-02, 1404/02/12**
Registration timing: **prospective**

Last update: **2025-05-02, 1404/02/12**
Update count: **0**

Registration date

2025-05-02, 1404/02/12

Registrant information

Name

Saeideh Soltani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date
2026-05-22, 1405/03/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effects of intra-articular injection of platelet-rich plasma (PRP) on pain and function of patients with knee osteoarthritis and comparison of the efficacy between moderate and severe degrees of knee osteoarthritis based on the Kellgren Lawrence classification

Public title
Evaluation of the effects of intra-articular injection of platelet-rich plasma (PRP) on patients with knee osteoarthritis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People between 40 and 80 years old. People with knee pain who have a VAS score of at least 4 on a standing knee radiograph and at least grade 2 osteoarthritis according to the Kellogg-Lawrence criteria, and who have received supportive treatment for at least 3 months and have not responded to treatment.
Exclusion criteria:
Pregnancy or breastfeeding Active cancer active infectious disease Drug or drug addiction History of any knee surgery or major trauma (leading to traumatic injury to the ligaments or meniscus or articular cartilage) Blood and coagulation diseases and use of anticoagulants Known rheumatological disease and fibromyalgia Use of anti-inflammatory medications and supplements (NSAIDs, corticosteroids, vitamins E and C, curcumin, and omega-3) within a week before and after the injection Having a significant physical or mental illness that increases the risk of disruption to the study process History of receiving corticosteroids or PRP in the knee for at least the past 6 months Use of any analgesics and physiotherapy modalities within 72 hours prior to outcome assessment
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **82**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences
Street address
Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733141
Approval date
2025-02-23, 1403/12/05
Ethics committee reference number
IR.TUMS.IKHC.REC.1403.509

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
WOMAC questionnaire score
Timepoint
First visit, two months, and 6 months after the second injection
Method of measurement
WOMAC questionnaire

2

Description
pain(VAS)
Timepoint
First visit, two months, and 6 months after the second

injection

Method of measurement

Patients are asked to rate the overall pain intensity they experienced over the past 48 hours on a Visual Analogue Scale (VAS) from 1 to 100.

Secondary outcomes

1

Description

The 30 Second Sit to Stand Test

Timepoint

First visit and two months after the second injection

Method of measurement

the number of times a person can stand and sit without using the arm of a chair in 30 seconds

2

Description

40 metre fast-paced walk test

Timepoint

First visit and two months after the second injection

Method of measurement

The time it takes for a person to walk a distance of 40 meters at maximum speed without running.

Intervention groups

1

Description

Intervention group: intraarticlar injection of PRP in knee

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam khomeini hospital complex

Full name of responsible person

Saeideh Soltani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

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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

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

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Saeideh Soltani

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

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Latest degree

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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

No - There is not 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

The present research has been registered as a proposal for the thesis of the Sports Medicine Residency Program. The resulting thesis from this proposal, including all participant data, study protocol, statistical analyses, and the full study report encompassing all variables, will be submitted to Tehran University of Medical Sciences and the Department of Sports Medicine. It is noteworthy that, upon approval of the thesis, an article containing all the mentioned elements will be published in a journal relevant to the topic of the research. Please note that access to raw data not included in the final report or published article requires direct communication with the principal investigator of the stud

When the data will become available and for how long

A period of two years has been estimated for all stages of the study until its submission as a thesis. The data obtained from this research will be submitted for publication as an article after the thesis has been approved at the end of the two-year period. Access to the raw data not included in the final report or the published article will be possible after the article's publication through direct communication with the principal investigator of the study.

To whom data/document is available

The data obtained from this research will be available to all interested individuals, and there will be no restrictions on access.

Under which criteria data/document could be used

There are no restrictions on the use, publication, or further processing of the data from this study, provided that prior communication is established with the principal investigator via email or other means, and the necessary permission is granted by the principal investigator.

From where data/document is obtainable

To access the information of this study, the interested individual may contact the principal investigator via email or phone.

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

The permission to use the information will be granted to the interested individual as soon as the email is received or the phone contact is made, and the requested information will be promptly sent to the individual via email.

Comments