Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A comparative study of the effectiveness of prp and prf injections under ultrasound guidance in improving the symptoms and performance of patients with Osteoarthritis (Grade 2 and 3 according to the Kellgren-Lawrence classification)

Protocol summary

Study aim

comparative study of the effectiveness of prp and prf injections under ultrasound guidance in improving the symptoms and performance of patients with Osteoarthritis

Design

A controlled clinical trial with parallel groups, double-blind, randomized, phase 2 on 56 patients (28 in each group). The rand function of Excel software was used for randomization.

Settings and conduct

This clinical trial study will be conducted in 1404 AH in patients with knee osteoarthritis at Imam Khomeini Hospital, Tehran. Patient information including demographic information (age, gender, underlying disease, height and weight), knee function status will be collected and recorded. Then, patients will be randomly divided into two groups, one group will receive PRP and the other group will receive PRF injection under ultrasound guidance. All measurements will be taken in all patients in both groups before the intervention and at weeks 1, 4 and 12 after the intervention. The people who collected the software and performed the analysis will be blinded.

Participants/Inclusion and exclusion criteria

Patients aged 50 to 75 years who have knee OA grade 2 and 3 according to the Kellgren-Lawrence classification

Intervention groups

Patients aged 50 to 75 years who have knee OA grade 2 and 3i injection of PRP and PR according to the Kellgren-Lawrence classification PRP was injected into one group and PRF was injected into the other group.

Main outcome variables

Quality of life and knee range of motion.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190719044274N2**
Registration date: **2026-06-15, 1405/03/25**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-15, 1405/03/25**
Update count: **0**

Registration date

2026-06-15, 1405/03/25

Registrant information

Name

Shervin Shahinpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 7624

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-02, 1404/03/12

Expected recruitment end date

2026-09-11, 1405/06/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A comparative study of the effectiveness of prp and prf injections under ultrasound guidance in improving the symptoms and performance of patients with Osteoarthritis (Grade 2 and 3 according to the Kellgren-Lawrence classification)

Public title
A comparative study of the effectiveness of prp and prf injections under ultrasound guidance in improving the symptoms and performance of patients with Osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 50 to 75 years who have. Patients with knee osteoarthritis grade 2 and 3 according to the Kellgren-Lawrence classification

Exclusion criteria:
Exclusion criteria included systemic disease such as diabetes, immunodeficiency, collagen vascular disease, history of malignancy, active infection or wound in the knee, autoimmune diseases, disorders affecting platelets. Hemoglobin < 12 mg/dL or platelets < 150,000/microL, history of severe knee trauma Steroid injection in the knee 3 weeks before surgery, systemic steroid injection in the last 2 weeks Hemoglobin < 12 mg/dL or platelets < 150,000/microL, history of severe knee trauma

Age
From **50 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description
The random block model is a generative model for random networks. Randomization unit: individual Randomization layers if stratified randomization is used Randomization tool: such as a random number table

Blinding (investigator's opinion)
Triple blinded

Blinding description
The randomized block model is a generative model for two-group random networks. Randomization unit: individual Randomization tool: such as a random number table With the help of computers, random number tables are prepared. These tables have different names and types. These tables are actually rows and columns of numbers that are randomly determined by the computer. In double-blind studies, not only the participant is unaware of their placement in the intervention and control groups; the follow-up and analyst are also unaware of it.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee in Biomedical Research, Imam Khomeini Hospital, Tehran University of Medical Scienc

Street address
Keshavarz blvd

City
Tehran

Province
Tehran

Postal code
1417653761

Approval date
2026-02-24, 1404/12/05

Ethics committee reference number
IR.TUMS.IKHC.REC.1404.503

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
Improve knee mobility

Timepoint
2 weeks

Method of measurement
Numeric rating scale questionnaire

Secondary outcomes

1

Description
Range of motion
Timepoint
6 w
Method of measurement
Physical examination

Intervention groups

1

Description
Intervention group: Platelet-rich fibrin belongs to a new generation of hemoconcentrates obtained by centrifugation alone, which provide. GF does not require additives such as heparin or thrombin and allows for slow release. GF has the following bioactive properties: stimulation by PRF, in addition to proliferation, differentiation, chemotaxis and adhesion of stem cells, promotion of vascularization and immune processes, increased expression of alkaline phosphatase in stem cells, which leads to faster mineralization of newly formed tissue. It also contains transforming growth factor beta GF. It also causes direct mineralization and creates an epithelial barrier by the membrane (PDGF) and platelet-derived growth factor (TGF-β1). 15 PRF
Category
Treatment - Other

2

Description
Control group: PRP intra-knee injection PRP preparation method: To prepare PRP, 10 ml of venous blood sample will be taken by centrifugation at 3400 rpm for 15 minutes at room temperature using a Neuation swing rotor centrifuge and 3.5 ml of PRP will be produced. The test tubes will contain sodium citrate solution as an anticoagulant and autologous thrombin as an activator to promote platelet activation and conversion of fibrinogen to fibrin. For quality tests, 0.5 ml of the PRP sample will be sent to the laboratory and 3 ml will be used for ultrasound-guided injection.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
shervin shahinpour
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
no
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

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ebrahim Espahbodi
Position
Associate professor
Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
In the case of individual participant data (IPD) there is no plan to share the data.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available