

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

sshahinpour@student.tums.ac.ir

Recruitment status

recruiting

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	unaware of their placement in the intervention and control groups; the follow-up and analyst are also unaware of it.
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)	Placebo Not used
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	Assignment Parallel
Purpose Treatment	Other design features
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	Secondary Ids empty
Age From 50 years old to 75 years old	Ethics committees
Gender Both	1
Phase N/A	Ethics committee Name of ethics committee Ethics Committee in Biomedical Research, Imam Khomeini Hospital, Tehran University of Medical Scienc
Groups that have been masked • Outcome assessor • Data analyser	Street address Keshavarz blvd
Sample size Target sample size: 56	City Tehran
Randomization (investigator's opinion) Randomized	Province Tehran
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	Postal code 1417653761
Blinding (investigator's opinion) Triple blinded	Approval date 2026-02-24, 1404/12/05
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	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

shervin shahinpour

Street address

Keshavarz Blvd, Gharib Ave, Imam khomeini hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 912 467 8934

Email

Shervinshahinpour@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farhad Etezadi

Street address

Keshavarz Blvd, Gharib Ave, Imam khomeini hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 910 212 1843

Email

etezadi@tums.ac.ir

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

Street address

Keshavaraz Blvd, Gharib Ave, Imam khomeini hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 6119 0000

Email

Shervinshahinpour@gmail.com

Person responsible for scientific 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

Street address

Keshavaraz Blvd, Gharib Ave, Imam khomeini hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 6119 0000

Email

Shervinshahinpour@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shervin Shahinpour

Position

Fellowship of Pain medicine

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Keshavaraz Blvd, Gharib Ave, Imam khomeini hospital, Tehran

City

Tehran

Province

Tehran

Postal code

1416753955

Phone

+98 21 6119 0000

Email

Shervinshahinpour@gmail.com

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