

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Sep 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

##### 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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | unaware of their placement in the intervention and control groups; the follow-up and analyst are also unaware of it.                                               |
| <b>Scientific title</b><br>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)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Placebo</b><br>Not used                                                                                                                                         |
| <b>Public title</b><br>A comparative study of the effectiveness of prp and prf injections under ultrasound guidance in improving the symptoms and performance of patients with Osteoarthritis                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Assignment</b><br>Parallel                                                                                                                                      |
| <b>Purpose</b><br>Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Other design features</b>                                                                                                                                       |
| <b>Inclusion/Exclusion criteria</b><br><b>Inclusion criteria:</b><br>Patients aged 50 to 75 years who have. Patients with knee osteoarthritis grade 2 and 3 according to the Kellgren-Lawrence classification<br><b>Exclusion criteria:</b><br>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 | <b>Secondary Ids</b><br>empty                                                                                                                                      |
| <b>Age</b><br>From <b>50 years</b> old to <b>75 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Ethics committees</b>                                                                                                                                           |
| <b>Gender</b><br>Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | <b>1</b>                                                                                                                                                           |
| <b>Phase</b><br>N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>Ethics committee</b><br><b>Name of ethics committee</b><br>Ethics Committee in Biomedical Research, Imam Khomeini Hospital, Tehran University of Medical Scienc |
| <b>Groups that have been masked</b><br><ul style="list-style-type: none"><li>• Outcome assessor</li><li>• Data analyser</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Street address</b><br>Keshavarz blvd                                                                                                                            |
| <b>Sample size</b><br>Target sample size: <b>56</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | <b>City</b><br>Tehran                                                                                                                                              |
| <b>Randomization (investigator's opinion)</b><br>Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <b>Province</b><br>Tehran                                                                                                                                          |
| <b>Randomization description</b><br>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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Postal code</b><br>1417653761                                                                                                                                   |
| <b>Blinding (investigator's opinion)</b><br>Triple blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | <b>Approval date</b><br>2026-02-24, 1404/12/05                                                                                                                     |
| <b>Blinding description</b><br>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                                                                                                                                                                                                                                                                                    | <b>Ethics committee reference number</b><br>IR.TUMS.IKHC.REC.1404.503                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Health conditions studied</b>                                                                                                                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>1</b>                                                                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Description of health condition studied</b><br>Knee osteoarthritis                                                                                              |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>ICD-10 code</b><br>M17                                                                                                                                          |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>ICD-10 code description</b><br>Osteoarthritis of knee                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Primary outcomes</b>                                                                                                                                            |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>1</b>                                                                                                                                                           |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Description</b><br>Improve knee mobility                                                                                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Timepoint</b><br>2 weeks                                                                                                                                        |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Method of measurement</b><br>Numeric rating scale questionnaire                                                                                                 |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <b>Secondary outcomes</b>                                                                                                                                          |

## 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- $\beta$ 1). 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

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**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

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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**

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**Email**

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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