

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The Effect of Plasma Rich in Growth Factors on Meniscal Degeneration in Knee Osteoarthritis

#### Protocol summary

##### Study aim

Investigating the effect of PRGF on meniscal degeneration based on MRI findings

##### Design

A randomized controlled clinical trial with parallel groups, phase 3, on 52 patients. Random Allocation software will be used for randomization.

##### Settings and conduct

This randomized controlled clinical trial includes middle-aged patients with knee pain and evidence of meniscal degeneration on MRI. The knees are randomized to intervention and control group. The control group receives routine osteoarthritis treatment, and the intervention group receives two intra-articular injections of PRGF, one month apart, in addition to routine treatment. The patients' symptoms are evaluated before the treatment and 4 months after the treatment using KOOS questionnaire. MRI is performed before the treatment and 4 months after the treatment to evaluate meniscal degeneration.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: (1) Individuals with knee pain; (2) Age between 40 and 60 years; (3) Meniscal degeneration detected on MRI. Exclusion criteria: (1) History of significant knee trauma; (2) Biomechanical abnormalities of the knee; (3) Meniscus or ligament tears; (4) History of rheumatic diseases; (5) History of septic arthritis of the knee; (6) Systemic diseases or medications that affect platelet count or function; (7) Malignancy or any severe systemic disease.

##### Intervention groups

In the control group, routine treatments for knee osteoarthritis include anti-inflammatory medication (500 mg of Naproxen every 12 hours), reducing knee strain through lifestyle changes, and strengthening the quadriceps muscle. In the intervention group, routine treatments plus two intra-articular injections of PRGF, which will be administered one month apart.

##### Main outcome variables

Grade of meniscal degeneration on MRI

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210423051054N2**

Registration date: **2026-03-01, 1404/12/10**

Registration timing: **prospective**

Last update: **2026-03-01, 1404/12/10**

Update count: **0**

##### Registration date

2026-03-01, 1404/12/10

##### Registrant information

##### Name

Rasa Salmani Oshnari

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2223 1012

##### Email address

rasa\_salmani@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2026-03-06, 1404/12/15

##### Expected recruitment end date

2026-05-21, 1405/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The Effect of Plasma Rich in Growth Factors on Meniscal Degeneration in Knee Osteoarthritis

### Public title

The Effect of PRGF on Meniscal Degeneration

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Individuals with knee pain Age between 40 and 60 years  
Meniscal degeneration detected on MRI

#### Exclusion criteria:

History of significant knee trauma Biomechanical abnormalities of the knee Meniscus or ligament tears  
History of rheumatic diseases History of septic arthritis of the knee Systemic diseases or medications that affect platelet count or function. Malignancy or any severe systemic disease

### Age

From **40 years** old to **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **52**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this clinical trial, 52 patients will be randomly enrolled in the study. Random Allocation software will be used to randomly allocate the samples. Using this software, random sequences will be created. For concealment, the random allocation concealment method will be used. In this method, the created sequences will be recorded on cards and these cards will be placed inside sealed envelopes. Then, based on the order in which the eligible individuals entered the study, each envelope will be opened and their assigned number will be determined.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

### Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

### Street address

Shahid Beheshti University of Medical Sciences, Yaman St, Shahid Chamran Hwy

### City

Tehran

### Province

Tehran

### Postal code

1985717443

### Approval date

2023-03-05, 1401/12/14

### Ethics committee reference number

IR.SBMU.RETECH.REC.1401.849

## Health conditions studied

### 1

#### Description of health condition studied

Meniscal degeneration

#### ICD-10 code

M23.3

#### ICD-10 code description

Other meniscus derangements

## Primary outcomes

### 1

#### Description

Meniscal degeneration on MRI

#### Timepoint

Before treatment and 4 months after the start of treatment

#### Method of measurement

Magnetic Resonance Imaging

## Secondary outcomes

### 1

#### Description

Pain, clinical symptoms, activities of daily living, function, and quality of life

#### Timepoint

Before treatment and 4 months after the start of treatment

#### Method of measurement

KOOS questionnaire

## Intervention groups

### 1

#### Description

Control group: Routine treatments for knee osteoarthritis include anti-inflammatory medication (500 mg of Naproxen every 12 hours), reducing knee strain through

lifestyle changes, and strengthening the quadriceps muscle.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Routine treatments plus two intra-articular injections of PRGF, which will be administered one month apart.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Taleghani hospital

**Full name of responsible person**

Najmeh Sadad Bolandnazar

**Street address**

Taleghani Hospital, Yaman St, Shahid Chamran Hwy

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**Email**

n.sadat.bolandnazar@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

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Yaman St, Shahid Chamran Hwy

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info@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Rasa Salmani Oshnari

**Position**

Physiatrist

**Latest degree**

Specialist

**Other areas of specialty/work**

Physical Medicine

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Rasa Salmani Oshnari

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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**Postal code**

1989934148

**Phone**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available