

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 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

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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

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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

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

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Full name of responsible person

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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

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

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Position

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Latest degree

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Rasa Salmani Oshnari

Position

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Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

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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