Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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+98 21 2223 1012

Email address
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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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Tehran

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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

Street address
Taleghani Hospital, Yaman St, Shahid Chamran Hwy

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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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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 updating data

Contact

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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