

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Efficacy of intra-articular injection of a newly developed plasma rich in growth factors (PRGF) versus hyaluronic acid on pain and function of patients with knee osteoarthritis: A single-blinded randomized clinical trial

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Objectives: The aim of this study is to compare efficacy and safety of intra articular injection of newly developed plasma rich in growth factors (PRGF) versus hyaluronic acid patients with knee OA.

Last update: **2018-03-24, 1397/01/04**

Update count: **0**

Registration date

2018-03-24, 1397/01/04

Design

Study Design: Single blind Randomized clinical trial.

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

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Settings and conduct

Setting and Conduct: In this study a total of 60 patients with more than three months of chronic pain in the knee joints along with consistent imaging findings (Kellgren-Lawrence score of II&III) would be enrolled and randomly allocated into two groups of plasma rich in growth factors (PRGF) versus hyaluronic acid.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Participants: Patients suffering from mild to moderate knee OA referred to Shahid Modarres Hospital of Saadat Abad in Tehran in 2016.

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Interventions: A single injection of plasma rich in growth factors (PRGF) in one group and a hyaluronic acid in other group.

Main outcome variables

Outcome measuers: Patients would be evaluated at baseline and 8, 24 weeks & 12 months after injection for pain, stiffness and function using the Visual Analog Scale (VAS) and the Western Ontario and McMaster Universities Arthritis Index (WOMAC) questionnaire

Scientific title

Efficacy of intra-articular injection of a newly developed plasma rich in growth factors (PRGF) versus hyaluronic acid on pain and function of patients with knee

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130523013442N23**

Registration date: **2018-03-24, 1397/01/04**

osteoarthritis: A single-blinded randomized clinical trial	
Public title	Efficacy of intra-articular injection of a newly developed plasma rich in growth factors (PRGF) versus hyaluronic acid on pain and function of patients with knee osteoarthritis
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Age between 45-75 years Symptomatic knee OA with the pain aggravated by weight bearing Symptoms lasting for at least 6 months despite conservative treatment Kellgren-Lawrance radiology scoring system scores ranging from 2-3 Exclusion criteria: History of trauma , surgery or any invasive procedure in the affected joint during the past 6 months Mal-alignment in lower limbs and abnormal blood count or impaired coagulation test Pregnant women Patients who were under immunosuppressant treatments Those with an underlying systemic arthropathy (secondary OA) Patients been treated with angiotensin converting enzyme inhibitors (ACE I) and significant deficiency in glucose 6 - phosphate dehydrogenase (G6PD) level
Age	From 45 years old to 75 years old
Gender	Both
Phase	N/A
Groups that have been masked	Participant
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	In this study a total of 60 patients with more than three months of chronic pain in the knee joints along with consistent imaging findings (Kellgren-Lawrence score of II&III) would be enrolled and randomly allocated into two groups of plasma rich in growth factors (PRGF) versus hyaluronic acid
Blinding (investigator's opinion)	Single blinded
Blinding description	Random table number is used to randomize. This is a single blind study and patients are not aware of the type of injected drug.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty

Ethics committees	
1	
Ethics committee	
Name of ethics committee	Ethic Committee of Shahid Beheshti University of Medical Sciences
Street address	Shahid Beheshti University of Medical Sciences, Sahahid Arabi street, Yaman street, Shahid Chamran Highway
City	Tehran
Province	Tehran
Postal code	1985717443
Approval date	2017-12-31, 1396/10/10
Ethics committee reference number	IR.SBMU.MSP.REC.1396.645
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	Knee Pain
Timepoint	Before intervention, 6 months & 12months after intervention
Method of measurement	Change of WOMAC questionnaire scores
Secondary outcomes	empty
Intervention groups	
1	
Description	Intervention group 1: plasma rich in growth factor, knee intraarticular injection, 4 to 6 milliliter, 2 times, 3 weeks interval
Category	Treatment - Drugs

2

Description

Intervention group 2 : Hyaluronic acid (500,000 to 730000 Daltons), 3 times, weekly

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Seyed Ahmad Raeissadat

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyed Ahmad Raeissadat

Street address

Shahid Modarres Hospital, Kaj Square, Saadat Abad, Tehran, Iran

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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

Vice chancellor for research, 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

Physical Medicine and Rehabilitation Department, Shahid Beheshti University of Medical Sciences, Sch

Full name of responsible person

Pegah Yavari

Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for scientific inquiries

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Associate Professor of Physical Medicine and Rehabilitation department, Shahid Beheshti University of

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Specialist

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

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Position

Resident of Physical Medicine and Rehabilitation

Latest degree

Medical doctor

Other areas of specialty/work

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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