

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

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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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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