

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Assessment of platelet rich plasma intraarticular injection in clinical outcome and MRI findings in knee osteoarthritis

Protocol summary

Summary

The goal of this study is assessment of effect of platelet rich plasma in clinical outcome and MRI findings in patients with knee osteoarthritis which is designed as a single blinded RCT. Osteoarthritis (OA) is a highly prevalent, chronic, degenerative condition that generates a high expense. Inclusion criteria are pain or joint swelling and radiologic findings of joint destruction since 3 months ago based on knee osteoarthritis criteria of The ACR. exclusion criteria are patients under treatment of anticoagulant or anti platelet drugs ,NSAIDs and corticosteroid usage and MRI contraindications and etc .this study is pilot and according to a same study sample size is 40 .patients will randomized in 2 groups and cases receive 2 intraarticular knee injections of PRP with 4 weeks interval.control group receive only therapeutic exercise. before intervention and 6 months later,VAS and WOMAC questionnaires will be completed and cartilage lesion and signal change,bone marrow edema,synovitis and etc will be assessed by knee MRI with specific protocol and parameters. .

General information

Acronym

PRP:platelet rich plasma

IRCT registration information

IRCT registration number: **IRCT2014020413442N6**

Registration date: **2014-02-26, 1392/12/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-26, 1392/12/07

Registrant information

Name

Seyed Ahmad Raeissadat

Name of organization / entity

Modares Hospital

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2013-05-31, 1392/03/10

Expected recruitment end date

2013-09-23, 1392/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of platelet rich plasma intraarticular injection in clinical outcome and MRI findings in knee osteoarthritis

Public title

Assessment of platelet rich plasma injection in clinical outcome and MRI findings in patients with knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: arthralgia since past 3 months; radiologic evidence of articular damage (grade 1-4 of Kellgren-Lawrence scale) based on knee OA criteria of

ACR. Exclusion criteria: systemic diseases such as diabetes mellitus and collagen vascular disorders; history or presence of cancer or malignant disorders; any infection and active wound of the knee; presence of immunosuppressive, autoimmune and platelet disorders; treatment with anticoagulant and anti-platelet medications 10 days before injection; use of NSAIDs 2 days before injection; history of knee articular injections of corticosteroids 3 weeks or use of systemic corticosteroids 2 weeks before PRP injections; hemoglobin measures of less than 12 g/dl and platelet counts of less than 150,000 per micro liter; recent history of severe trauma to the knee; age less than 45 or over 75 year; history of vasovagal shock; pregnancy; breastfeeding; genu valgum/varum greater than 20 degrees; contraindication for MRI including aneurysm clips, pacemaker, metallic devices and claustrophobia.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

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

Postal code

Approval date

2012-10-28, 1391/08/07

Ethics committee reference number

124

Health conditions studied

1

Description of health condition studied

knee osteoarthritis

ICD-10 code

M17

ICD-10 code description

Gonarthrosis [arthrosis of knee]

Primary outcomes

1

Description

cartilage lesion

Timepoint

before intervention & 6 months after intervention

Method of measurement

WORMS criteria

2

Description

joint stiffness

Timepoint

before intervention & 6 months after intervention

Method of measurement

WOMAC questionnaire

3

Description

function

Timepoint

before intervention & 6 months after intervention

Method of measurement

WOMAC questionnaire

4

Description

knee pain

Timepoint

before intervention & 6 months after intervention

Method of measurement

WOMAC questionnaire

5

Description

knee pain

Timepoint

before intervention & 6 months after intervention

Method of measurement

VAS

6

Description

bone marrow edema

Timepoint

before intervention & 6 months after intervention

Method of measurement

WORMS criteria

7

Description

meniscus lesion

Timepoint

before intervention & 6 months after intervention

Method of measurement

WORMS criteria

8

Description

synovitis

Timepoint

before intervention & 6 months after intervention

Method of measurement

WORMS criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : platelet rich plasma, knee intraarticular injection, 4 to 6 milliliter, 2 times, 4 weeks interval

Category

Treatment - Drugs

2

Description

Control group:exercise,quadriceps strengthening and hamstring stretching,10 times for 10 seconds,3 times a day

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Elham Ghorbani

Street address

Shahid Modarres Hospital, Kaj square, Saadat Abad street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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

Full name of responsible person

Vice chancellor for research, Seyed Ahmad Raeissadat

Street address

Physical Medicine and Rehabilitation Department, Shahid Modarres Hospital, Kaj square, Saadat abad

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid modarres hospital

Full name of responsible person

Elham Ghorbani

Position

Physical Medicine and Rehabilitation resident

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Shahid Modarres Hospital

Full name of responsible person

Seyed Ahmad Raeissadat

Position

Assistant Professor

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty