

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Evaluation of efficacy of treatment with stem cells (SCs) and platelet-rich plasma (PRP) in patients with knee osteoarthritis

Protocol summary

Summary

This study is a randomized controlled trial on 60 human subjects with grade 2 and 3 knee osteoarthritis (according to plain radiography) who will be enrolled according to inclusion and exclusion criteria. Patients will be randomly distributed into 4 groups of 15 patients. The initial MRI will be performed for all patients and the patients will be treated as follow: 1) intra-articular injection of mesenchymal cells or MSCs (treatment group) that are isolated from the abdominal wall adipose tissue 2) intra-articular injection of platelet-rich plasma or PRP (treatment group) that are extracted from 100 mL of peripheral blood 3) Intra-articular injection of MSCs in PRP-rich medium (treatment group) and 4) intra-articular injection of hyaluronic acid (control group) which is commercially available. Patients' follow-ups will be at month 1, 3, 6 and 12 post-treatment. At each follow-up, a clinical examination including range of motion and crepitus of the knee as well as an assessment of patient's health with KOOS (Knee injury and Osteoarthritis Outcome Score) questionnaire and NRS (Numerical Rating Scale) will be performed. Another MRI (second MRI) and a plain standing radiograph of the knee (second radiograph) at 6th month post-injection will be done and the results will be read according to MOAKS (Magnetic resonance imaging Osteoarthritis Knee Score) and K&L (Kellgren and Lawrence) scales. Following the last follow-up, the collected data will be compared and analyzed in a way that firstly, the findings of each patient in each group before and after the intervention will be independently compared, and secondly, the results of each group will be compared with the other three groups.

General information

Acronym

S

IRCT registration information

IRCT registration number: **IRCT2012080510507N1**

Registration date: **2014-06-01, 1393/03/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-01, 1393/03/11

Registrant information

Name

Zhaleh Shariati Sarabi

Name of organization / entity

Department of Internal Medicince, Imam Reza Hospital

Country

Iran (Islamic Republic of)

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+98 51 1802 2370

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2013-08-23, 1392/06/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of efficacy of treatment with stem cells (SCs) and platelet-rich plasma (PRP) in patients with knee

osteoarthritis

Public title

Evaluation of efficacy of treatment with stem cells (SCs) and platelet-rich plasma (PRP) in patients with knee arthrosis

Purpose

Treatment

Inclusion/Exclusion criteria

INCLUSION CRITERIA: Female or male patient with knee osteoarthritis based on the ACR criteria and knee radiography; Grade 2 or 3 osteoarthritis according to Kellgren and Lawrence grading scale; 45 < Patient's Age < 75; Signed informed consent; No consumption of glucocorticoids, anti-inflammatory and immunomodulatory medications one week prior to the treatment; No history of previous participating in clinical trials on treatment of osteoarthritis; No intra-articular injection of hyaluronic acid in the past 6 months
EXCLUSION CRITERIA: Secondary osteoarthritis; Concurrent connective tissue disorder; Active neurological disease; Severe cardiac disease; Debilitating respiratory disease requiring constant treatment; Any endocrinopathy; Malignancies; Current infectious disease; Psychologic diseases (especially major depression) requiring treatment with antidepressants or related medications; Being under treatment with immunosuppressive or cytotoxic medications; Being under constant treatment with antithrombotic medications; History of allergy to biologic products; Hb < 11 g/dL; Plt < 120*103/ μ L

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Daneshgah St.

City

Mashhad

Postal code

913791-3316

Approval date

2013-02-06, 1391/11/18

Ethics committee reference number

511/4436

Health conditions studied

1

Description of health condition studied

Knee Osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

Primary outcomes

1

Description

Morphological characteristics of of articular cartilage

Timepoint

Before intervention, 6 months post-intervention, 12 months post-intervention

Method of measurement

MRI Osteoarthritis Knee Score (MOAKS)

2

Description

Pain

Timepoint

Before intervention, 1 month post-intervention, 3 months post-intervention, 6 months post-intervention, 12 months post-intervention

Method of measurement

Pain Numerical Scale Rating

3

Description

Symptoms and function of the affected knee

Timepoint

Before intervention, 1 month post-intervention, 3 months post-intervention, 6 months post-intervention, 12 months post-intervention

Method of measurement

Knee injury and Osteoarthritis Outcome Score (KOOS)

4

Description

Range of motion

Timepoint

Before intervention, 1 month post-intervention, 3 months post-intervention, 6 months post-intervention, 12 months post-intervention

Method of measurement

Angle with protractor

Secondary outcomes

empty

Intervention groups

1

Description

Intra-articular injection of 2 mL hyaluronan (scaffold) + 2 mL autologous mesenchymal stem cell (2-3 million) + 0.2 mL dexamethasone

Category

Treatment - Drugs

2

Description

Intra-articular injection of 2 mL hyaluronan (scaffold) + 2 mL autologous platelet rich plasma + 0.2 mL dexamethasone

Category

Treatment - Drugs

3

Description

Intra-articular injection of 2 mL hyaluronan (scaffold) + 2 mL autologous mesenchymal stem cell (2-3 million) + 2 mL autologous platelet rich plasma + 0.2 mL dexamethasone

Category

Treatment - Drugs

4

Description

Intra-articular injection of 2 mL hyaluronan + 0.2 mL dexamethasone

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Tayebeh Asadi Sakhmareshi

Street address

Ibn Sina st.

City

Mashhad

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr. Sara Jalali Jivan

Street address

Ibn Sina st.

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Immunology Research Center

Full name of responsible person

Dr. Mahmoud Mahmoudi

Street address

Immunology Research Center, Bu-Ali Research Institute, Bu-Ali Square,

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Immunology Research Center

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Headquarter of Research and Application of Stem Cells

Full name of responsible person

Dr. Ali Ghasemi

Street address

Montaserieh Organ Transplantation Office, Golestan St., Imam Khomeini Ave.

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Headquarter of Research and Application of Stem Cells

Proportion provided by this source

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

Bu-Ali Research Institute

Full name of responsible person

Dr. Jalil Tavakol Afshari

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Web page address

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