

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)

Phone

+98 51 1802 2370

Email address

shariatij@mums.ac.ir

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
Immunologist
Other areas of specialty/work
Street address
Bu-Ali Square
City
Mashhad
Postal code
9196773117
Phone
+98 51 1711 2611
Fax
Email
TavakolAJ@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Department of Internal Medicine, Imam Reza Hospital
Full name of responsible person
Dr. Zhaleh Shariati Sarabi
Position
Rheumatologist
Other areas of specialty/work
Street address
Ibn Sina st.

City
Mashhad
Postal code
Phone
+98 51 1802 2370
Fax
Email
shariatij@mums.ac.ir; jshariati@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Medical Office
Full name of responsible person
Dr. Seyed Mostafa Monzavi
Position
Medical Doctor
Other areas of specialty/work
Street address
#24, 2nd Farhad St., Malekabad Blv.
City
Mashhad
Postal code
9185757779
Phone
+98 51 1768 2983
Fax
Email
seyedmostafamonzavi@gmail.com
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