

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Evaluation of Effectiveness of Intra-Articular Injection of Bone Marrow Derived Stem Cells for Treatment of Degenerative Knee Osteoarthritis

#### Protocol summary

##### Summary

In this randomized controlled trial, 30 human subjects with grade 2 and 3 knee osteoarthritis (according to plain radiography) will be enrolled according to inclusion and exclusion criteria. Patients will be randomly distributed into 2 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 bone marrow derived mesenchymal cells or MSCs (treatment group) 2) intra-articular injection of commercially available hyaluronic acid gel (control group). 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) will be done at 6th month post-injection and the results will be read according to modified MOCART (Magnetic Resonance Observation of Cartilage Repair Tissue) 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 group.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021710507N4**

Registration date: **2016-02-20, 1394/12/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-02-20, 1394/12/01

##### Registrant information

###### Name

Zhaleh Shariati Sarabi

###### Name of organization / entity

Department of Internal Medicincine, 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

2015-09-23, 1394/07/01

##### Expected recruitment end date

2016-09-23, 1395/07/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of Effectiveness of Intra-Articular Injection of Bone Marrow Derived Stem Cells for Treatment of Degenerative Knee Osteoarthritis

##### Public title

Evaluation of Effectiveness of Intra-Articular Injection of Stem Cells on 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/ $\mu$ L

**Age**

From **45 years** old to **75 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**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**

2015-02-06, 1393/11/17

**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**

Modified version of "Magnetic Resonance Observation of Cartilage Repair Tissue" (Modified MOCART)

**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

**5**

**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 bone-marrow derived mesenchymal stem cell (2-3 million) + 0.2 mL dexamethasone

**Category**

Treatment - Drugs

**2**

**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. Ali Yaghoubi

**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. Mashhad

**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**

Headquarter of Research and Application of Stem Cells

**Full name of responsible person**

Dr. Ali Ghasemi

**Position**

Immunologist

**Other areas of specialty/work****Street address**

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

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**Postal code****Phone**

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## 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****Phone**

00

**Fax****Email****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 3802 2370

## 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*