

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

The effects of intra-articular injection of mesenchymal stem cells on improvement of pain and physical function in patients with knee joint osteoarthritis -An interventional double blind randomized clinical trial phase II

Protocol summary

Summary

Study Objects: Osteoarthritis is a degenerative disease of the joint cartilage, which often affects the subchondral bone. In this study, the effects of intra articular injection of bone marrow derived autologous mesenchymal stem cells on pain relief and physical function of moderate to severe knee osteoarthritis will be evaluated. **Study design and method:** In a double blind randomized placebo-controlled phase II study, 48 patients with chronic knee osteoarthritis who visited in orthopedics clinic of Shahid Madani hospital and Royan cell therapy center, would be assessed through two groups including the case group (20 millions autologous mesenchymal stem cells in two doses) and the placebo group. **Participants:** Patients in a range of 18 to 65 years old who have been diagnosed to have osteoarthritis through MRI, and are not suffered from other chronic diseases and cancer, would be studied. **Interventions:** Intraarticular transplantation of 20 millions of mesenchymal stem cells in two doses in the case group; placebo injection in the control group **Outcome variables:** It would be tried to reduce the pain and improve the physical function of the patients and increase the damaged cartilage thickness through intraarticular transplantation of autologous bone marrow derived mesenchymal stem cells. The follow ups would be included: Radiographic findings, VAS (Visual Analogue Scale), WOMAC (Western Ontario and McMaster Universities Osteoarthritis index-pain, physical function and stiffness sub scores) questionnaire, MRI and Walking Distance (WD).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507061031N1**

Registration date: **2016-06-30, 1395/04/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-30, 1395/04/10

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell Biology and Technology

Expected recruitment start date

2012-12-25, 1391/10/05

Expected recruitment end date

2015-10-31, 1394/08/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of intra-articular injection of mesenchymal stem cells on improvement of pain and physical function in patients with knee joint osteoarthritis -An interventional double blind randomized clinical trial phase II

Public title

Transplantation of stem cells in knee joint osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients in the range of 18 to 65 years old; Osteoarthritis diagnosed by MRI Exclusion Criteria: Pregnancy or lactating; Positive tests for HIV, HCV, HBV; Active neurologic disorder; End organ damage; History/active malignancy; Uncontrolled endocrine disorder; Active respiratory disorder/reaction to sedation drugs; History of cancer

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

blocking

Secondary Ids

1

Registry name

ClinicalTrials.gov

Secondary trial Id

NCT01504464

Registration date

2012-01-03, 1390/10/13

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Royan infertility institute

Street address

Royan institute, Eastern Hafez St,Northern Banihashem St, 45 m Resalat highway

City

Tehran

Postal code

Approval date

2011-07-12, 1390/04/21

Ethics committee reference number

EC/90/1026

Health conditions studied

1

Description of health condition studied

Knee joint osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Primary gonarthrosis, bilateral

2

Description of health condition studied

Knee joint osteoarthritis

ICD-10 code

M17.1

ICD-10 code description

Other primary gonarthrosis Primary gonarthrosis: • NOS
• unilateral

Primary outcomes

1

Description

Function improvement

Timepoint

3,6,12 and 30 months after transplantation

Method of measurement

WOMAC osteoarthritis index

2

Description

Pain density

Timepoint

3,6,12 and 30 months after transplantation

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Cartilage thickness

Timepoint

6,12 and 30 months after transplantation

Method of measurement

MRI

2

Description

Subchondral edema

Timepoint

6,12 and 30 months after transplantation

Method of measurement

MRI

3

Description

Joint function

Timepoint

6,12 and 30 months after transplantation

Method of measurement

Physical examination, VAS, womac

4

Description

Allergic reactions

Timepoint

3,6,12and 30 month after transplantation

Method of measurement

Physical examination

5

Description

Neoplastic changes

Timepoint

6,12 and 30 months after transplantation

Method of measurement

MRI

Intervention groups

1

Description

Case group: Biological: Intraarticular transplantation of 20 millions autologous bone marrow mesenchymal stem cells in 3 to 5 ml N/S in two doses which will be injected in 0 and 12 months.

Category

Treatment - Other

2

Description

Control group: Biological: Placebo Patients with knee joint osteoarthritis who underwent intra articular placebo injection

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinic of Shahid Madani Hospital

Full name of responsible person

Dr Mohsen Emadaldin

Street address

Orthopedic Clinic of Shahid Madani Hospital, Shahid Madani Sq., Mahan Blv.

City

Karaj

2

Recruitment center

Name of recruitment center

Royan Cell Therapy Center

Full name of responsible person

Hamid Gourabi

Street address

Royan Institute, Eastern Hafez St,Northern Banihashem St, Resalat highway 45 meters

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Hamid Gourabi

Street address

Eastern Hafez St,Northern Banihashem St, 45 m Resalat highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Royan Institute

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

Royan Institute

Full name of responsible person

Shahedeh Karimi Torshizi

Position

M.D/ Researcher

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

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Royan Cell Therapy Center

Full name of responsible person

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Position

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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