Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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
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Iran (Islamic Republic of)
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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
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Shahedeh Karimi Torshizi

Position
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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