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
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Royan Institute
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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

Secondary outcomes

1
Description
Pain density

Timepoint
3,6,12 and 30 months after transplantation

Method of measurement
Visual Analogue Scale
Description
Subchondral edema
Timepoint
6, 12 and 30 months after transplantation
Method of measurement
MRI

Description
Joint function
Timepoint
6, 12 and 30 months after transplantation
Method of measurement
Physical examination, VAS, Womac

Description
Allergic reactions
Timepoint
3, 6, 12 and 30 months after transplantation
Method of measurement
Physical examination

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 intraarticular 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

Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Royan Institute
Full name of responsible person
Hamid Gourabi
Street address
Royan Institute, Eastern Hafez St, Northern Banihashem St, Resalat highway 45 meters
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
Country of origin
empty
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Royan Institute
Full name of responsible person
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Position  
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Other areas of specialty/work

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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