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 autologus 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 autologus 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 autologus 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
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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
Cartilage thickness
Timepoint
6, 12 and 30 months after transplantation
Method of measurement
MRI
### 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 Blvd.

### 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
Royan Institute

### 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

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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