Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect And Safety Of Allogenic Placental Mesenchymal Stem Cells In Treatment Of Knee Osteoarthritis, Pilot Study

Protocol summary

Summary

The study is designed as a double blind clinical trial,in which neither the subject nor the person administering the treatment nor the person evaluating the response to treatment knows which treatment any particular subject is receiving.20 patients of knee osteoarthritis based on inclusion and exclusion criteria will join the study. After primary evaluations including VAS, KOOS questionnaire, clinical examination and MRA (magnetic resonance arthrography) they will be randomized by sealed envelope methode in 2 case and control groups .10 patients in Case group will receive 50 million placental mesenchymal stem cells which collected and prepared in standard conditions, in a single intraarthicular injection while the control group will receive intraarthicular injection of PBS (Phosphate Buffered Saline) in a sterile setting. Evaluations after the injection are clinical signs of inflammation till 30 minutes after injection, VAS, KOOS questionnaire and clinical examination at 2 weeks, 2 months and 6 months and paraclinical (MRA) at 6 months after injection.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101823298N2**
Registration date: **2016-03-16, 1394/12/26**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-03-16, 1394/12/26

Registrant information

Name

Mohamad Vasei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8490 2187

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research,Iran University Of Medical Science Vice chancellor for research,Tehran University Of Medical Science

Expected recruitment start date

2015-11-22, 1394/09/01

Expected recruitment end date

2016-03-21, 1395/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect And Safety Of Allogenic Placental Mesenchymal Stem Cells In Treatment Of Knee Osteoarthritis, Pilot Study

Public title

Mesenchymal Stem Cells In Treatment Of Knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: knee osteoarthritis based on ACR (American College of Rheumatology) criteria and grade 1,2,3 based on Kellgren-Lawrence grading scale; Ability to follow during the study period exclusion criteria: age

<18 and >75 years; presence of any acute or chronic infectious process; knee deformity (varus >10 ° or valgus >20°); impaired renal function(creatinine>2.0 mg/dl); impaired liver function(Bilirubin > 2.0 □/□, AST/ALT > 100 IU/L); Pregnancy or lactating; neoplasia; BMI>35; Immunosuppressive state; Systemic autoimmune rheumatic disease or secondary osteoarthritis; intraarthicular injections in last 3 months; history of knee surgery; Poorly controlled diabetes mellitus

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **20**

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
Ethics committee of Iran University of Medical Science

Street address
Medical faculty, Iran University of Medical Science, Hemmat High way,Tehran

City
Tehran

Postal code
1449614535

Approval date
2015-07-06, 1394/04/15

Ethics committee reference number
IR . IUMS . rec .1394 . 9311524003

Health conditions studied

1

Description of health condition studied
osteoarthritis

ICD-10 code
M19.0

ICD-10 code description
Primary arthrosis NOS

Primary outcomes

1

Description
KOOS value

Timepoint
before,2 months and 6 months after injection

Method of measurement
KOOS questionnaire

2

Description
VAS value

Timepoint
before,2 weeks,2 months and 6 months after injection

Method of measurement
VAS

3

Description
knee range of motion

Timepoint
before,2 weeks,2 months and 6 months after injection

Method of measurement
goniometer

4

Description
radiologic MRA parameters

Timepoint
before and 6 months after injection

Method of measurement
MRA(magnetic resonance arthrography)

Secondary outcomes

1

Description
clinical sign and symptoms of inflammatory and allergic reactions

Timepoint
before,30 minute,2 weeks,2 months and 6 month after injection

Method of measurement
physical examination(swelling, erythema, skin rash, fever, effusion)

Intervention groups

1

Description

10 patients in case group will receive 50 million placental mesenchymal stem cells in a single intraarthicular injection.

Category

Treatment - Other

2

Description

10 patient in the control group will receive single intraarthicular injection of PBS (Phosphate Buffered Saline) in a sterile setting.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Doctor Shayesteh Sadat Khalifesoltani

Street address

Firoozgar hospital, Beh-Afarin alley, Valiye-Asr square,Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For Research Of Tehran University of Medical Science

Full name of responsible person

Doctor Mohammad Vasei

Street address

Ghods street,Keshavarz blvd., Vice Chancellor For Research Of Tehran University of Medical Science ,Tehran

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Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor For Research Of Tehran University of Medical Science

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

Vice Chancellor For Research Of Iran University of Medical Science

Full name of responsible person

Doctor Bijhan Forough

Street address

Iran University of Medical Science, Hemmat High way,Tehran

City

Tehran

Grant name

Grant code / Reference number

-

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

Yes

Title of funding source

Vice Chancellor For Research Of Iran University of Medical Science

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

Iran University of Medical Science

Full name of responsible person

Doctor Shayesteh Sadat Khalifesoltani

Position

physical medicine and rehabilitation resident

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