

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The Effect And Safety Of Allogenic Adipose-Derived 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 method in 2 case and control groups. 10 patients in Case group will receive 30 million allogenic adipose-derived mesenchymal stem cells from young healthy donors which collected and prepared in standard conditions, in a single intraarticular injection while the control group will receive intraarticular 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: **IRCT2016021123298N3**

Registration date: **2016-02-20, 1394/12/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-20, 1394/12/01

Registrant information

Name

Mohamad Vasei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8490 2187

Email address

mvasei@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University Of Medical Science

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect And Safety Of Allogenic Adipose-Derived 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 μmol/L, AST/ALT > 100 IU/L); Pregnancy or lactating; neoplasia; BMI>35; Immunosuppressive state; Systemic autoimmune rheumatic disease or secondary osteoarthritis; intraarticular 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

Approval date

2016-01-24, 1394/11/04

Ethics committee reference number

IR.IUMS.REC.1394.26914

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 weeks,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 30 million adipose-

derided mesenchymal stem cells in a single intraarticular injection.

Category

Treatment - Other

2

Description

10 patient in the control group will receive single intraarticular 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

City

Tehran

Sponsors / Funding sources

1

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

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

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

Street address

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

City

Tehran

Postal code

Phone

+98 21 86701

Fax

Email

shayesteh_khalifesoltani@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Doctor Bijhan Forough

Position

physical medicine and rehabilitation specialist

Other areas of specialty/work

Street address

Iran University of Medical Science, Hemmat highway, Tehran

City

Tehran

Postal code

Phone

+98 21 8862 2600

Fax

Email

bforough@tums.ac.ir

Web page address

Person responsible for updating data

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

Street address

Iran University of Medical Science, Hemmat High way, Tehran

City

Tehran

Postal code**Phone**

+98 21 8862 2600

Fax**Email****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