

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Sep 2026

Evaluation of safety and efficacy of intra-articular transplantation of allogeneic adipose derived mesenchymal stromal cells in patients with knee joint osteoarthritis An interventional randomized triple-blind placebo controlled clinical trial phase I/II

Protocol summary

Study aim

Evaluation of safety and efficacy of intra-articular transplantation of allogeneic adipose-derived mesenchymal stem cells on pain relieving and physical activity improvement, in patients with knee joint osteoarthritis.

Design

A triple-blind randomized controlled clinical trial phase I/II

Settings and conduct

First we will recruit 3 patients with osteoarthritis admitted in orthopedic clinic of shafa yahyaiean hospital evaluating safety of allogeneic adipose derived mesenchymal stem cells, and if there were no serious side effects after 3 months, another 90 patients in two groups: case group (allogeneic adipose derived MSCs) and control group (normal saline) will be studied in terms of their positive effects in pain reduction and improvement in physical function.

Participants/Inclusion and exclusion criteria

Patients with 18 to 65 years old Whose arthritis is detected with MRI and are not affected with chronic diseases or cancer, are recruited.

Intervention groups

Intra-articular transplantation of 100 millions of allogeneic adipose-derived mesenchymal stromal cells in case group and injection of 3-5 ml NL/S in control group

Main outcome variables

evaluation of allogeneic adipose derived MSCs transplantation on pain and patient' physical activity and the thickness of affected cartilage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080728001031N23**

Registration date: **2018-04-24, 1397/02/04**

Registration timing: **registered_while_recruiting**

Last update: **2021-08-26, 1400/06/04**

Update count: **1**

Registration date

2018-04-24, 1397/02/04

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 2356 2000

Email address

nasser.aghdami@royaninstitute.org

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-14, 1395/12/24

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and efficacy of intra-articular

transplantation of allogeneic adipose derived mesenchymal stromal cells in patients with knee joint osteoarthritis An interventional randomized triple-blind placebo controlled clinical trial phase I/II

Public title

Allogeneic stem cell transplantation 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 central or peripheral neurologic disorder End organ damage or Uncontrolled endocrine disorder Active respiratory disorder and reaction to sedative drugs history of cancer

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomized allocation to intervention and control groups

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants would be allocated in case and control groups according to a confidential table of accidental numbers which will be just available for the lab responsible. Care provider, investigator and outcome assessor are not aware of the substance which injected. In order to eliminate data analyzer's errors, group types would not be uncovered until the results are determined.

Placebo

Used

Assignment

Parallel

Other design features

Block randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Royan infertility institute

Street address

Eastern Hafez St,Northern Banihashem St, 45 m Resalat highway

City

Tehran

Province

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Postal code

1665659911

Approval date

2017-10-10, 1396/07/18

Ethics committee reference number

IR.ACECR.ROYAN.REC.1396.138

Health conditions studied

1

Description of health condition studied

cell therapy in osteoarthritis

ICD-10 code

M15.9

ICD-10 code description

Polyosteoarthritis, unspecified

Primary outcomes

1

Description

Side effects

Timepoint

One week, one month, 3, 6 and 12 months after transplantation

Method of measurement

Physical examination, adverse effect questionnaire

2

Description

Joint function

Timepoint

Before, 3, 6 and 12 months after transplantation

Method of measurement

WOMAC and KOOS questionnaires for osteoarthritis

Secondary outcomes

1

Description

Cartilage thickness

Timepoint

Before and 12 months after transplantation

Method of measurement

MRI

2

Description

Molecular and cellular indexes (IL-6, IL-10, TNF- α , IFN- γ , COMP, CTX-II, HA, CS846, CD4, CD3, CD8, CD25)

Timepoint

Before, one week, 3 and 6 months after transplantation

Method of measurement

Blood test

3

Description

Subchondral edema

Timepoint

Before and 12 months after transplantation

Method of measurement

MRI

4

Description

Joint effusion

Timepoint

Before and 12 months after transplantation

Method of measurement

MRI

5

Description

new cartilage formation

Timepoint

Before and 12 months after transplantation

Method of measurement

MRI

Intervention groups

1

Description

Phase I and case group in phase II: intraarticular transplantation of single dose 100 millions of allogeneic adipose derived mesenchymal stem cells

Category

Other

2

Description

Control group (phase II): intraarticular transplantation of single dose 3 to 5 ml normal saline as placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinic of Shafa Yahyaeian hospital

Full name of responsible person

Dr. Abolfazl Bagheri fard

Street address

Mojahedin e islam street, Baharestan Square

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bagherifard@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Abdol hossein Shahverdi

Street address

Eastern Hafez St, Northern Banihashem St, 45 m Resalat highway

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shahverdi@royaninstitute.org

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

90

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Sponsor**Name of organization / entity**

Shafa Yahyaeian Hospital

Full name of responsible person

Abolfazl Bagheri fard

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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

Shafa Yahyaeian Hospital

Proportion provided by this source

10

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Royan cell therapy center

Full name of responsible person

Shahedeh Karimi Torshizi

Position

M.D/ Researcher

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Email**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Royan Institute

Full name of responsible person

Nasser Aghdami

Position

M.D,Ph.D

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for updating data**Contact****Name of organization / entity**

Royan Institute

Full name of responsible person

Hoda Madani

Position

Researcher/M.D

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable