

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of therapeutic effect of placental mesenchymal stem cell exosome injection in improving clinical symptoms and MRI changes in patients with knee osteoarthritis

Protocol summary

Study aim

Evaluation of therapeutic effect of placental mesenchymal stem cell exosome injection in improving subjective symptoms and objective imaging findings in patients with knee osteoarthritis

Design

Clinical trial with control group, with parallel groups, triple blinded, randomized, phase 3 on 30 patients.

Settings and conduct

In this triple blinded clinical trial, patients with osteoarthritis of the knee referred Taleghani hospitals were randomly divided into two groups of 30 patients. Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Lequesne Index as well as Visual Analogue Scale (VAS) are completed for patients. All patients undergo X-ray imaging and MRI of the knee. The intervention group received exosome injection and exercise therapy, and the control group received normal saline injection and exercise therapy. The mentioned questionnaires, in addition to the time before the intervention, will be completed at the end of months 2 and 6 for all patients. At the end of month 6, MRI of the knees is repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) pain in both knees during the last 6 months, 2) graphic confirmation of bilateral knee osteoarthritis with grade 2 or 3; Exclusion criteria: 1) younger than 45 years or older than 65 years, 2) any intra-articular injection of the knee during the last 3 months

Intervention groups

Patients in the intervention group received 5 cc of exosome in the knee joint, and the control group received 5 cc of normal saline. Knee strengthening and stretching exercises are taught to patients in both groups.

Main outcome variables

VAS; WOMAC Index; Lequesne index; Patellofemoral cartilage volume; Tibiofemoral cartilage volume; Knee joint synovitis; Internal and external meniscus disintegration; Patellofemoral cartilage erosion; Tibiofemoral cartilage erosion; Anterior cruciate ligament injury

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210423051054N1**

Registration date: **2022-05-11, 1401/02/21**

Registration timing: **prospective**

Last update: **2022-05-11, 1401/02/21**

Update count: **0**

Registration date

2022-05-11, 1401/02/21

Registrant information

Name

Rasa Salmani Oshnari

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-06-22, 1401/04/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of therapeutic effect of placental mesenchymal stem cell exosome injection in improving clinical symptoms and MRI changes in patients with knee osteoarthritis

Public title

The effect of exosomes in the treatment of knee osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pain in both knees over the past 6 months, which is related to the degenerative process of the knee, requires pain medication and has lasted for more than a month. Graphical confirmation of bilateral knee osteoarthritis with grade 2 or 3 based on the Kellgren-Lawrence classification. The knee pain intensity should be greater than or equal to 4 according to the VAS.

Exclusion criteria:

Younger than 45 years or older than 65 years Rheumatic or collagen vascular disease History of malignancy Coagulopathy or taking anticoagulant drug Any injection into the knee joint during the last 3 months A history of recent severe knee trauma in the past 1 month Septic arthritis of the knee or active wound of the knee joint Genovorum or genovalgum greater than 20 degrees Total knee replacement Cardiac pacemaker Cochlear implantation Existence of fragments or foreign metal object in the knee or around the arteries, nerves and brain

Age

From **45 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **30**

More than 1 sample in each individual

Number of samples in each individual: **2**

One knee as intervention and the other knee as control

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial study, 30 patients with bilateral

osteoarthritis of the knee, referred to the physical medicine and rehabilitation clinic of Taleghani Hospital in Tehran, will be randomly entered into the study. Random Allocation software will be used for random assignment of samples. Random sequences from 1 to 30 will be created using this software. Random allocation concealment method will be used for hiding. In this way, the created sequences are recorded on cards and these cards will be placed in sealed envelopes. Then, according to the order of entry of eligible people to study, each envelope will be opened and their assigned number will be determined. Thus, if the desired number was even, the right knee will be selected as the intervention and the left knee as the control, and if the desired number is odd, the left knee will be selected as the intervention and the right knee as the control.

Blinding (investigator's opinion)

Triple blinded

Blinding description

According to the codings performed for patients and drugs, all patients, caregivers, data collector, people who evaluate the outcomes, as well as data analyzer, for the intervention performed in each patient (drug or Placebo) are unaware. Both knees of the patient are injected. Drug is injected in one knee and placebo in the other, randomly.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

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Shahid Beheshti University of Medical Sciences, Yaman St, Shahid Chamran Hwy

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Approval date

2022-03-08, 1400/12/17

Ethics committee reference number

IR.SBMU.MSP.REC.1400.773

Health conditions studied

1

Description of health condition studied

Knee osteoarthritis

ICD-10 code

M17.0

ICD-10 code description

Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description

Pain intensity

Timepoint

Before intervention, 2 and 6 months after intervention

Method of measurement

Visual Analogue Scale

2

Description

Pain intensity, stiffness, and physical activity

Timepoint

Before intervention, 2 and 6 months after intervention

Method of measurement

Western Ontario and McMaster Universities Osteoarthritis Index

3

Description

Pain or discomfort, maximum distance walked, and activities of daily living

Timepoint

Before intervention, 2 and 6 months after intervention

Method of measurement

Lequesne Index

4

Description

Patellofemoral cartilage volume

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging

5

Description

Tibiofemoral cartilage volume

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging

6

Description

Knee joint synovitis

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging

7

Description

Medial and lateral meniscus disintegration

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging

8

Description

Patellofemoral cartilage erosion

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging

9

Description

Tibiofemoral cartilage erosion

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging

10

Description

Anterior cruciate ligament injury

Timepoint

Before intervention and 6 months after intervention

Method of measurement

Magnetic resonance imaging

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Injection of 5 cc of placental mesenchymal stem cell exosome into the knee with anterolateral approach in the flexed position, isometric strengthening exercises for quadriceps, adductor and abductor muscles of the thigh (10 times and each time for 10 seconds), 2 times a day, and stretching of hamstrings (3 times and each time for 30 seconds), 2 times a day.

Category

Treatment - Drugs

2

Description

Control group: Injection of 5 cc of normal saline into the knee with anterolateral approach in the flexed position, isometric strengthening exercises for quadriceps, adductor and abductor muscles of the thigh (10 times and each time for 10 seconds), 2 times a day, and stretching of hamstrings (3 times and each time for 30 seconds), 2 times a day.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

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Sponsors / Funding sources

1

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Name of organization / entity

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rasa Salmani Oshnari

Position

Resident

Latest degree

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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

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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