

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### Mesenchymal stem cell injection in patients with knee osteoarthritis compared to a randomized controlled trial

#### Protocol summary

##### Study aim

Determination of therapeutic effect of injection under the guidance of adipose mesenchymal cell sonography with control group in patients with knee osteoarthritis

##### Design

Clinical trial including control group and factorial groups, and in two-way blind, will randomly perform. This study carry out in phase 3 with 80 patients.

##### Settings and conduct

Adipose tissue from the superficial layer of the abdomen will be removed during liposuction from 25 to 35 years old with personal consent. This surgery is performed in Hazrat Rasoul Akram Hospital (Iran, Tehran). Stem cells are separated from fat according to the protocol and injected into intervention groups. The collected data for each patient are recorded in the patient profile and finally statistical analysis of the data will be performed using SPSS 20 software.

##### Participants/Inclusion and exclusion criteria

Input criteria include the following: 1. Knee osteoarthritis based on the American College of Rheumatology criteria, in Grade 1,2,3 corresponds to the Lawrence and Kellgren criteria. 2. Knee pain for at least six months And inclusion criteria are included Absence of inflammatory inflammatory diseases of the joint or secondary osteoarthritis 2. Absence of local or systemic infectious process 3. Do not perform intra-articular injections during the last trimester 4. No history of knee surgery

##### Intervention groups

80 people are selected with the mentioned entry and non-entry conditions. Individuals are divided into 20 blocks of 4. in each group 1 person is selected randomly as control group. and 3 people of each block are randomly selected for fat-derived stem cell injection.

##### Main outcome variables

Cartilage thickness as measured using MRI results; Pain assessed using the VAS test; The range of motion of flexion and extension of the knee is assessed using a goniometric test.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20210307050611N1**

Registration date: **2021-05-22, 1400/03/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-05-22, 1400/03/01**

Update count: **0**

##### Registration date

2021-05-22, 1400/03/01

##### Registrant information

##### Name

Naser Amini

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8608 3674

##### Email address

amini\_ot@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-22, 1400/02/02

##### Expected recruitment end date

2022-04-22, 1401/02/02

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  |                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Mesenchymal stem cell injection in patients with knee osteoarthritis compared to a randomized controlled trial                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | Factorial                                                                                                                                                                                                                                                                                                                                                            |
| <b>Public title</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  | <b>Other design features</b>                                                                                                                                                                                                                                                                                                                                         |
| Mesenchymal stem cell injection in patients with knee osteoarthritis compared to a randomized controlled trial                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | <b>Secondary Ids</b>                                                                                                                                                                                                                                                                                                                                                 |
| <b>Purpose</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | empty                                                                                                                                                                                                                                                                                                                                                                |
| Treatment                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |  | <b>Ethics committees</b>                                                                                                                                                                                                                                                                                                                                             |
| <b>Inclusion/Exclusion criteria</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  | <b>1</b>                                                                                                                                                                                                                                                                                                                                                             |
| <b>Inclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | <b>Ethics committee</b>                                                                                                                                                                                                                                                                                                                                              |
| Knee Osteoarthritis Based on American College of Rheumatology Criteria in Grades 1, 2, and 3: Lowrence - Kellergan Knee pain for at least six months Proper liver function (Bilirubin $\leq 2.0$ $\square/\square$ , AST/ALT $\leq 100$ IU/L) Proper renal function (Creatinine $\leq 2.0$ $\square/\square$ )                                                                                                                                                                                                                                                                                                    |  | <b>Name of ethics committee</b>                                                                                                                                                                                                                                                                                                                                      |
| <b>Exclusion criteria:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | Ethics Committee of Iran University of Medical Sciences                                                                                                                                                                                                                                                                                                              |
| Any acute or chronic infection Pregnancy or decision to become pregnant Any intra-articular injection during the last three months Inflammatory joint disease or secondary osteoarthritis History of knee surgery Severe underlying disease such as uncontrolled diabetes, taking anticoagulants Daily use of opioid and non-opioid analgesics                                                                                                                                                                                                                                                                    |  | <b>Street address</b>                                                                                                                                                                                                                                                                                                                                                |
| <b>Age</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | Iran University of medical science. beside of Milad tower. Hemmat highway                                                                                                                                                                                                                                                                                            |
| From <b>18 years</b> old to <b>60 years</b> old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <b>City</b>                                                                                                                                                                                                                                                                                                                                                          |
| <b>Gender</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | Tehran                                                                                                                                                                                                                                                                                                                                                               |
| Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |  | <b>Province</b>                                                                                                                                                                                                                                                                                                                                                      |
| <b>Phase</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |  | Tehran                                                                                                                                                                                                                                                                                                                                                               |
| 3                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  | <b>Postal code</b>                                                                                                                                                                                                                                                                                                                                                   |
| <b>Groups that have been masked</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |  | 1449614535                                                                                                                                                                                                                                                                                                                                                           |
| <ul style="list-style-type: none"> <li>• Outcome assessor</li> <li>• Data analyser</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | <b>Approval date</b>                                                                                                                                                                                                                                                                                                                                                 |
| <b>Sample size</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |  | 2021-04-18, 1400/01/29                                                                                                                                                                                                                                                                                                                                               |
| Target sample size: <b>80</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | <b>Ethics committee reference number</b>                                                                                                                                                                                                                                                                                                                             |
| <b>Randomization (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |  | IR.IUMS.REC.1400.064                                                                                                                                                                                                                                                                                                                                                 |
| Randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |  | <b>Health conditions studied</b>                                                                                                                                                                                                                                                                                                                                     |
| <b>Randomization description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |  | <b>1</b>                                                                                                                                                                                                                                                                                                                                                             |
| After being selected according to the entry criteria, individuals receive a numeric code from one to eighty, then to form blocks of 4, eligible individuals are randomly divided into 20 groups by naming the letters of the alphabet. In each block with letters alphabetically, one person is selected randomly and the third person is selected by lottery, and this person is selected as the control group of each block, and in each block, the remaining three people are considered as the intervention group. It should be noted that this type of random selection is done by lottery method and blind. |  | <b>Description of health condition studied</b>                                                                                                                                                                                                                                                                                                                       |
| <b>Blinding (investigator's opinion)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | Knee osteoarthritic                                                                                                                                                                                                                                                                                                                                                  |
| Double blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | <b>ICD-10 code</b>                                                                                                                                                                                                                                                                                                                                                   |
| <b>Blinding description</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |  | M17,                                                                                                                                                                                                                                                                                                                                                                 |
| The study is a double-blind clinical trial. Primary blinding: Outcome evaluation tests are performed by an expert before and after the intervention. The relevant expert is unaware of how to block, select the subjects and the tests related to them. The relevant expert is unaware of the studied groups and this test is performed by a physical medicine and rehabilitation physiatrist.                                                                                                                                                                                                                    |  | <b>ICD-10 code description</b>                                                                                                                                                                                                                                                                                                                                       |
| <b>Placebo</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |  | Osteoarthritis of knee                                                                                                                                                                                                                                                                                                                                               |
| Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |  | <b>Primary outcomes</b>                                                                                                                                                                                                                                                                                                                                              |
| <b>Assignment</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |  | <b>1</b>                                                                                                                                                                                                                                                                                                                                                             |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <b>Description</b>                                                                                                                                                                                                                                                                                                                                                   |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | Pain: The pain assessment scale is performed by the VAS test. In this questionnaire, which is filled in by the participant before the intervention and six months after the intervention, the least pain in the last trimester is zero and the number 10 is considered as the highest pain in the last trimester. Scores between zero and 10 for the amount of pain. |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <b>Timepoint</b>                                                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | Before intervention and 6 months after injection                                                                                                                                                                                                                                                                                                                     |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <b>Method of measurement</b>                                                                                                                                                                                                                                                                                                                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | VAS questionnaire                                                                                                                                                                                                                                                                                                                                                    |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |  | <b>Secondary outcomes</b>                                                                                                                                                                                                                                                                                                                                            |

## 1

### **Description**

Pain due to inflammation in the knee joint in the last 6 months

### **Timepoint**

Before the intervention and 6 months later

### **Method of measurement**

The VAS questionnaire is filled out by the patient for the amount of pain and the patient scores from 0 to 10 according to the amount of pain.

## 2

### **Description**

The range of motion of the knee joint from the extent position to 140 degrees is measured in both active and passive forms.

### **Timepoint**

Before intervention and 6 months after injection

### **Method of measurement**

Goniometer

## 3

### **Description**

Knee cartilage formation using MRI image

### **Timepoint**

Before intervention and 6 months after injection

### **Method of measurement**

MRI image of the knee in a supine position

## **Intervention groups**

## 1

### **Description**

Cell therapy is a branch of modern regenerative medicine that uses autologous or allogeneic stem cells to treat many untreated diseases, including knee osteoarthritis. Stem cells are prepared for cell therapy in a sterile and clean environment. In this study, 8 million adipose-derived stem cells in two milliliters of normal saline were injected into each patient's knee under an ultrasound guide. Before the stem cell injection, a two-hour session is considered to explain and teach the patient the treatment method, satisfaction as well as post-injection care. After selecting the patient to study, the time required for patient availability is eight months. Adipose-derived stem cells after isolation, culture, characterization and quality control tests are performed in a clean room with grade A and B clean room of Motahhari Hospital and under sterile conditions, by experts in this field.

### **Category**

Treatment - Other

## 2

### **Description**

Control group: A quarter of all patients in the control group will be evaluated clinically and radiologically at intervals of one and six months. These patients will be

given knee care training in daily life activities and to participate in this. The project must be submitted so that during this period they will not receive any other therapeutic intervention. If they receive any therapeutic intervention, inform the project manager to remove them from the project. Tests for goniometry, pain, cartilage thickness will be taken at intervals of one to six months.

### **Category**

Treatment - Other

## **Recruitment centers**

## 1

### **Recruitment center**

#### **Name of recruitment center**

Sports Medicine Center of Hazrat Rasoul Hospital

#### **Full name of responsible person**

Parisa Nejati

#### **Street address**

Hazrat rasoul Hospital. Sattarkhan street

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

1449614535

#### **Phone**

+98 21 8608 3674

#### **Email**

parisanejati2@gmail.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Iran University of Medical Sciences

#### **Full name of responsible person**

Naser Amini

#### **Street address**

Hemmat Highway, next to Milad Tower. Iran University of Medical Sciences

#### **City**

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#### **Province**

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#### **Phone**

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#### **Email**

Amini\_ot@yahoo.com

### **Grant name**

Research Assistant Iran University of Medical Sciences

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Iran University of Medical Sciences

**Proportion provided by this source**

50

**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**

Iran University of Medical Sciences

**Full name of responsible person**

Naser amini

**Position**

Assistance professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

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

Iran University of Medical Sciences

**Full name of responsible person**

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**Position**

professor assistant

**Latest degree**

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**Other areas of specialty/work**

Cell therapy

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

Iran University of Medical Sciences

**Full name of responsible person**

Naser Amini

**Position**

Assistance professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Neuroscience

**Street address**

Mottahari Hospital. yasemi street. Valiasr avenue

**City**

Tehran

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no more information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available