# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Jul 2026

## Evaluation of weight bearing exercises on pain and physical function of patients with knee osteoarthritis treated by implantation of autologous bone marrow derived mesenchymal stromal cells.

## Protocol summary

**Study aim**

Evaluation of the effect of weight-bearing and non-weight-bearing exercises on pain and function in patients with osteoarthritis of the knee treated with bone marrow-derived mesenchymal stromal cells

**Design**

This clinical trial consisted of two parallel groups, one-way blind, randomized, on 40 patients to perform movements with weighting and without weighting on the knee joint. Stratified Block Randomization is used for randomization.

**Settings and conduct**

This trial will be performed on 40 patients with knee osteoarthritis who have undergone stromal cell therapy at Royan Institute. Patients are randomly divided into two groups of 20 and for one group weight bearing exercises with on the knee joint and in the second group exercises without weight bearing will be performed. Exercises will be described to patients by the physician and will be evaluated and compared before, 1 month after, and 3 months after the intervention. The project will be implemented in Taleghani Hospital. Only the statistical analyzer will be blind to the type of treatment.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Patients with osteoarthritis of the knee treated by autologous bone marrow derived mesenchymal stromal cells; Non-entry conditions: Uncontrolled diseases that interfere with the intervention process. For example, the patient may not be able to attend regular exercise therapy sessions to pursue treatment for his or her uncontrolled disease.

**Intervention groups**

Group A: Weigh bearing Exercises Group B: None weigh bearing Exercises

**Main outcome variables**

Patient pain and functional status

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20180226038870N2**
Registration date: **2021-03-11, 1399/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2021-03-11, 1399/12/21**
Update count: **0**

**Registration date**

2021-03-11, 1399/12/21

**Registrant information**

**Name**

Narges Labibzadeh

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 2233 9949

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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2021-01-20, 1399/11/01

**Expected recruitment end date**

2022-01-21, 1400/11/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**
Evaluation of weight bearing exercises on pain and physical function of patients with knee osteoarthritis treated by implantation of autologous bone marrow derived mesenchymal stromal cells.

**Public title**
"Evaluation if weight bearing exercises on patients with knee osteoarthritis treated by stromal cells"

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Knee osteoarthritis of grade 2 or 3 diagnosed by MRI and confirmed by orthopedics surgeon. Less than one month before enrollment in the present study, the patient underwent intra-knee implantation of bone marrow-derived mesenchymal stromal cells. Aged between 18-65 years old.

**Exclusion criteria:**
Uncontrolled medical situations which need frequent medical treatment and therefore patient will be unable regularly participate in follow up sessions of current trial, such as cancers and autoimmune diseases. Pregnancy and lactating

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

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**

- Data analyser

**Sample size**
Target sample size: **40**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The method of assigning the subjects after applying the entry and exit criteria will be random allocation by permutation block method. The randomization unit is individual. The size of the blocks is 4 and in each block, each intervention group will be repeated twice. As a result, we will have 6 different blocks, each of which will be numbered from 1 to 6 as desired. Then, using the rdunif statistical program code (n = 10, b = 6, a = 1) in R software version 3.6.1, 10 blocks of 4 will be generated, which will produce a total of 40 sequences. (It should be noted that this code generates ten random numbers from the numbers 1 to 6, which are the number of blocks). Using this randomly generated list, patients will be placed in the intervention group (exercise therapy with weight bearing) and the control group (exercise therapy without weight bearing). To hide the random allocation list, a special code will be assigned to each of the intervention groups that only the main executor of the project is aware of. These codes are written on a piece of paper and placed in a sealed envelope. A unique code that is specific to each patient will be written on this paper as well as its envelope. A foil is also placed inside each envelope so that the envelopes are not legible under light. Each envelope also contains a white paper and a carbon. All envelopes are placed in a larger box in random order and will be sealed in the box. The main researcher, after reviewing the inclusion criteria and obtaining informed consent, as well as registering the patient's details in a special form, will contact the partner who has a random assignment list (except for the main researcher who is not involved in the patient recruitment and sample entry process). And the patient is randomized. Also, before opening the envelope, this person must write the name and surname and age of the person on the place marked on the envelope so that its copy falls on the paper inside the envelope.

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**
In this study, due to the nature of this trial, that requires exercise by volunteers, only statistical analyzer blinding will be possible, and volunteers and the evaluating physician who works with both groups of patients are not blind to it. Before the person enters the study, the physician in charge of the project will fully explain to the patient that the people will be randomly placed in each of the two groups and the patient will be fully aware of this. Finally, the statistical analyzer whom will be blind to the data , will analyze it and will not know which treatment protocol is included for each person.

**Placebo**
Not 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

**Street address**
Taleghani hospital Arabi Ave, Shahid Chamran Blvd. Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
1985711151

**Approval date**
2020-06-02, 1399/03/13

**Ethics committee reference number**
IR.SBMU.MSP.REC.1399.086

## Health conditions studied

**1**

**Description of health condition studied**
Knee Osteoarthritis
**ICD-10 code**
M17
**ICD-10 code description**
Osteoarthritis of knee

## Primary outcomes

**1**

**Description**
Pain on Visual Analogue Scale
**Timepoint**
Measurement of patients' pain in the knee joint according to Visual Analogue Scale criteria before the intervention and 1 month and 3 months after the intervention
**Method of measurement**
Pain on Visual Analogue Scale

## Secondary outcomes

**1**

**Description**
Patients physical function based on Western Ontario and McMaster Universities Osteoarthritis Index
**Timepoint**
Before intervention and 1 and 3 months after intervention
**Method of measurement**
Using Western Ontario and McMaster Universities Osteoarthritis Index questionnaire

**2**

**Description**
Patient walking distance
**Timepoint**
Before intervention and 1 and 3 months after intervention
**Method of measurement**
Based on the patient interview

**3**

**Description**
Standing time
**Timepoint**
Before intervention and 1 and 3 months after intervention
**Method of measurement**
Based on the patient interview

**4**

**Description**
Patient quality of life
**Timepoint**
Before intervention and 1 and 3 months after intervention
**Method of measurement**
The 36-Item Short Form Survey (SF-36)

## Intervention groups

**1**

**Description**
Intervention group: In the group receiving exercises with weight bearing (group A), the exercise sessions are as follows: Aerobic exercises include: walking 3 days a week with moderate intensity for 30 minutes daily for the first 1 month, during the Second month: 40 minutes daily and finally 45 minutes daily in the last month. Type: Walking Strength training (on days when aerobic exercise is not done) Includes: For quadriceps 4 days a week with an average intensity of 5 out of 10 or until Patient to be tired. Type: Semi Scott. To strengthen the lower limbs: 4 days a week with moderate intensity: 5 out of 10 or until tired. 30 repetitions per leg, 10 repetitions Type: Balance. To strengthen the lower limbs: 4 days Medium intensity per week: 5 out of 10 or until tired. Type: cuff raise. in the first month with both feet and then as a single foot.
**Category**
Treatment - Other

**2**

**Description**
Intervention group: In the receiving group Exercise without weight bearing (group B) Exercise sessions are as follows: Aerobic: 3 days a week with moderate intensity on a scale of 5 out of 10 for 30 minutes daily for the first month, 40 minutes daily in the second month and finally 45 Minutes per day in the third month. Type: Walking in the pool. For resistance in days when aerobic exercise is not done. Isometric quadriceps contraction: 4 days a week with moderate intensity: 5 out of 10 or until tired. 3 sets with 8 seconds contraction with 10 repetitions Type: quadratic isometric contraction. Then to strengthen the lower limbs 4 days a week medium intensity, 5 of 10 or until he is tired. 8 seconds of contraction: 3 sets of 30 degrees of knee flexion in the prone position, and after being able to bear weight of the same leg for 8 seconds, put the opposite leg on this leg and train with the weight of both legs. . To strengthen the lower limbs 4 days a week on average: 5 out of 10 or until tired: 2 sets with 8 seconds of contraction with 10 repetitions per foot: Type: Plantar Flexion and dorsiflexion.
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Taleghani hospital

**Full name of responsible person**
Mohammad Hassabi
**Street address**
Arabi Ave, Shahid Chamran Blvd, Tehran
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**Province**
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**Postal code**
1985711151
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**Email**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Afshin Zarghi
**Street address**
Arabi Ave, Shahid Chamran Blvd, Tehran
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Tehran
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**Phone**
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**Email**
zarghi@sbmu.ac.ir
**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**
Mohammad Hassabi
**Position**
Associated professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Sport Medicine
**Street address**
Arabi Ave, Shahid Chamran Blvd, Tehran
**City**
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**Province**
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**Postal code**
1985711151
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ddrnlz@gmail.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
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**Position**
Associated professor
**Latest degree**
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## Person responsible for updating data

**Contact**
**Name of organization / entity**
Shahid Beheshti University of Medical Sciences
**Full name of responsible person**
Narges Labibzadeh
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Sport Medicine
**Street address**
Arabi Ave, Shahid Chamran Blvd, Tehran
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**Province**

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**Postal code**

1985711151

**Phone**

+98 21 2243 2560

**Email**

ddrnlz@gmail.com

## Sharing plan

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

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

After the end of the study, all the data related to the study, including the main and secondary consequences, will be shared after Unidentifiable the individuals.

**When the data will become available and for how long**

Access starts 6 months after the results are published

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

The released data can only be used for scientific use by other researchers, and the use of the data will be allowed only with the permission of the physician in charge of this project.

**From where data/document is obtainable**

Arabi Ave, Shahid Chamran Blvd, Tehran Mohammad Hassabi 0098 021 22432560 hassabi@yahoo.com

**What processes are involved for a request to access data/document**

The doctor in charge will be contacted first, after coordination with him, they will receive information via e-mail or in person at their discretion. This process will take 1 to 2 weeks.

**Comments**