Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Email address

ddrnlz@gmail.com

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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ddrnlz@gmail.com

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
Postal code
1985711151
Phone
+98 21 2243 9331
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
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Arabi Ave, Shahid Chamran Blvd, Tehran
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
Mohammad Hassabi
Position
Associated professor
Latest degree
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Other areas of specialty/work
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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
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Resident
Latest degree
Medical doctor
Other areas of specialty/work
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1985711151

Phone

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Email

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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