

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Effect of Cell Therapy on the Clinical Signs and symptoms of Patients with Severe knee Osteoarthritis: Pilot study

Protocol summary

Study aim

Effect of Cell Therapy on the Clinical Signs and symptoms of Patients with Severe knee Osteoarthritis

Design

By random sampling method, based on a random number table Among Patients Referred to the orthopedic clinic, since the start of the project, 5 patients selected on the basis of clinical, para-clinical findings and Kellgren-Lawrence grades 2- 4 osteoarthritis that they will be selected by the physician's decision.

Settings and conduct

Patients with knee osteoarthritis referring to Orthopedic Clinic of Urmia Imam Khomeini Hospital.

Participants/Inclusion and exclusion criteria

Patients with grade 2 to 4 osteoarthritis who do not have other underlying conditions and do not consume tobacco.

Intervention groups

Stem cells extracted from each patient inject himself.

Main outcome variables

Signs and symptoms of Osteoarthritis are including morning pain and stiffness, decrease joint flexion, joint swelling and Arthritis and joint deformities.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180102038184N1**

Registration date: **2018-12-29, 1397/10/08**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-29, 1397/10/08**

Update count: **0**

Registration date

2018-12-29, 1397/10/08

Registrant information

Name

sahar mehranfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3235 9094

Email address

mehranfar.s@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2021-04-30, 1400/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Cell Therapy on the Clinical Signs and symptoms of Patients with Severe knee Osteoarthritis: Pilot study

Public title

Effect of Cell Therapy on knee Osteoarthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Have grade 2-4 knee osteoarthritis 2. They have been taken Corticosteroids and NSAIDs for a long time, but due to its side effects , they are not able to take these group of pills. 3. Although Corticosteroids and NSAIDs have been taken for 3 months, significant improvement has not been observed in sense of pain. 4. Being in the

range of 18- 85- year-old

Exclusion criteria:

1. There are have blood diseases, cancers, AIDS, and hepatitis. 2- Taking Immunosuppressive drugs for the last 6 months; NSAIDs, ASA within 7 days ago; Plavix, Warfarin within 3 days ago. 3- Tobacco users. 4- Being pregnant or breastfeeding mothers 5 - Have immune system disease 6 - BMI less than 30 7 - Susceptible to lidocaine and epinephrine 8 - Have other joint disease, such as chondrocalcinosis, rheumatoid arthritis, gout, fibromyalgia, lupus,... 9- Have a knee joint surgery up to a year ago 10 - Have arthritis in the pelvis, shoulder... 11 - Unable to tolerate the pain without taking pain killer pills for 5-7 days before each medical visit.

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **5**

More than 1 sample in each individual

Number of samples in each individual: **5**
ten

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Orjhans Street., Resalat Blvd., Urmia University of Medical Science, Urmia., Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-08-16, 1397/05/25

Ethics committee reference number

IR.UMSU.REC.1397.164

Health conditions studied

1

Description of health condition studied

osteoarthritis

ICD-10 code

M17

ICD-10 code description

Osteoarthritis of knee

Primary outcomes

1

Description

Score of signs and symptoms of knee osteoarthritis according to koos (Knee injury and Osteoarthritis Outcome Score) questionnaire

Timepoint

1,3,6 months after and 1 year after

Method of measurement

Magnetic Resonance Imaging (MRI) , Knee injury and Osteoarthritis Outcome Score (KOOS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Isolated Mesenchymal stem cells that extracted from Patient's adipose tissue injected only once with 1,000,000 cells into intra-articular knee joint by an Orthopedic surgeon.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Emam khomeini Hospital

Full name of responsible person

Sahar Mehranfar

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Orjhans Street., Resalat Blvd., Urmia University of Medical Science

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Sahar Mehranfar

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Sahar Mehranfar

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

cell therapy, cancer diagnosis in early stage

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Sahar Mehranfar

Position

Assist. Prof

Latest degree

Ph.D.

Other areas of specialty/work

cell therapy

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Person responsible for updating data

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Sahar Mehranfar

Position

Academic staff

Latest degree

Ph.D.

Other areas of specialty/work

cell therapy

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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

The whole data can be shared after being unidentified and after the end of the study

When the data will become available and for how long

After the article is published

To whom data/document is available

All academic researchers

Under which criteria data/document could be used

Future studies

From where data/document is obtainable

The executor of the plan

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

Formal email from academic email

Comments