Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical evaluation of osteochondral regeneration using autologous chondrocytes seeded in bilayered

Protocol summary

Summary

Cartilage tissue engineering applications commonly encompass the use of three-dimensional scaffolds to provide a suitable microenvironment for the incorporation of cells or growth factors to regenerate damaged tissues. Silk fibroin scaffolds are typically porous, biocompatible and biodegradable materials that support physical and biochemical stimuli for optimal cell growth and function. In addition, over the last years autologous chondrocyte transplantation (ACT) as an advanced, cell-based technology, use for the treatment of chondral defects of the knee. The purpose of this trial is to evaluate the safety and effectiveness of the autologous chondrocytes seeded in bilayered scaffolds based on silk fibroin and collagen in presence of growth factors in the treatment of osteochondral lesions located on the femoral condyle of the patients in phase 1 and 2 clinical trial during 24 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062434731N1**
Registration date: **2017-07-27, 1396/05/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-07-27, 1396/05/05

Registrant information

Name
Manijeh Khanmohammadi
Name of organization / entity
Avicenna Research Institute
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Recruitment status

Recruitment complete

Funding source

Avicenna Research Institutescientific and technological department of presidential office

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2019-07-23, 1398/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of osteochondral regeneration using autologous chondrocytes seeded in bilayered

Public title

Clinical evaluation of of osteochondral regeneration using silk fibroin and collagen scaffolds

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: female or male; within the age range of 18 to 65 years; symptomatic osteochondral lesion of the medial or lateral femoral condyles with ICRS grade 3-4 lesion. Exclusion Criteria: meniscus removal with surgical treatment; knee non corrected instability; diagnosis with metastatic diseases or malignant diseases; pregnancy or breast feeding, history of neurological disease; history of endocrinological disorders such as diabetes; history of pulmonary heart diseases; infectious diseases such as

hepatitis B and C, HIV and history of allergic diseases.

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

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Avicenna Research Institute

Street address
Avicenna Research Institute, Shahid Beheshti University, Evin, PO Box 19615-1177

City
Tehran

Postal code
1936773493

Approval date
2017-05-23, 1396/03/02

Ethics committee reference number
IR.ACECR.Avicenna.REC.1396.4

Health conditions studied

1

Description of health condition studied
Osteochondral defects

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Radiological and Clinical Studies

Timepoint
Before intervention and 6 months and 1 year after intervention

Method of measurement
Radiographic images

2

Description
MRI studies

Timepoint
Before intervention and 6 months and 1 year after intervention

Method of measurement
MRI results

Secondary outcomes

1

Description
Pain in the surgical area

Timepoint
after intervention

Method of measurement
Based on available evidence

Intervention groups

1

Description
Evaluation of the safety and effectiveness of the autologous chondrocytes seeded in bilayered scaffolds based on silk fibroin and collagen in presence of growth factors in the treatment of osteochondral lesions located on the femoral condyle of the patients in phase 1 and 2 clinical trial during 24 months.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shariati Hospital

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Avicenna Research Institute

Full name of responsible person

Dr Somaieh Kazemnejad

Street address

Avicenna Research Institute, Shahid Beheshti University, Evin, PO Box 19615-1177

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Avicenna Research Institute

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

scientific and technological department of presidential office

Full name of responsible person

Musavinejad

Street address

No,. 20, Ladan alley, North Sheikh Bahayee St., MollaSadra St., Vanak Sq

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

scientific and technological department of presidential office

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Avicenna Research Institute

Full name of responsible person

Dr Somaieh Kazemnejadi

Position

Clinical Biochemistry

Other areas of specialty/work

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Manijeh khanmohammadi

Position

Master of science

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty