Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of Transplantation of Mesenchymal Stem Cells and Autologous Chondrogenic Pre-Differentiated Mesenchymal Stem Cells for the Treatment of Cartilage Lesions of knee joint

Protocol summary

Summary

The aim of the present study was to transplant autologous chondrogenic pre-differentiated mesenchymal stem cells to treat patients with knee cartilage lesions. For this purpose, 16 patients aged between 15 and 40 with joint cartilage injuries (lesion size between 2.5 and 6 cm in internal or external femoral condylar) are included in this study. The selected individuals should not have any metabolic, infectious, and malnutrition or have not used any special medication. Sixteen patients are selected, which then devided into two groups; a control group that receives only synovial mesenchymal stem cells and a treatment group that receives chondrogenic pre-differentiated mesenchymal stem cells. After transplantation, patients were evaluated for improvement at 3, 6, 12, and 18 weeks after treatment by arthroscopy and MRI. At the end of the course, a synovial fluid was sampled and joint biopsy was performed to determine the biochemical factors such as glycosamineglycans, hydroxyproline. Gene and protein expression, like aggrecan, collagen type 2 and sox9 are also investigated using Real-time PCR and immunocytochemistry.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017052634053N2**
Registration date: **2017-07-13, 1396/04/22**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-07-13, 1396/04/22

Registrant information

Name
Gholamreza Ghorbani Amjad
Name of organization / entity
Hamadan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Hamedan University of Medical Sciences

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Transplantation of Mesenchymal Stem Cells and Autologous Chondrogenic Pre-Differentiated Mesenchymal Stem Cells for the Treatment of Cartilage Lesions of knee joint

Public title

The use of stem cells for the treatment of the cartilage lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged between 15 years to 40 years; the lesion between 2.5 and 6 square centimeters; the lesions of trauma sports and non-sports injury; femoral condyle internal or external lesions Exclusion criteria: Obesity; corticosteroid injection less than 3 months ago; hyaluronic acid injection less than 6 months ago; varus and valgus more than 5 degree; diabetes type one and two; autoimmune disease; malnutrition; certain neurological diseases; history of allergy; infectious diseases

Age
From **15 years** old to **40 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **16**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan University of Medical Sciences

Street address
Hamadan University of Medical Sciences, Shahid Fahmideh Blvd, Hamadan, Iran

City
Hamadan

Postal code

Approval date
2017-04-22, 1396/02/02

Ethics committee reference number
IR.UMSHA.REC.1396.81

Health conditions studied

1

Description of health condition studied
Destructive lesions of the knee joint cartilage

ICD-10 code
M94.9

ICD-10 code description
Disorder of cartilage, unspecified

Primary outcomes

1

Description
Articular cartilage lesions of the knee

Timepoint
3.6.12,18 weeks

Method of measurement
MRI and diagnostic arthroscopy

Secondary outcomes

1

Description
glycosaminoglycans, collagen, gene and protein expression of, agercan, collagen type II and sox9

Timepoint
Eighteenth week

Method of measurement
biochemical, molecular and immunocytochemistry analysis

Intervention groups

1

Description
Control group: This group will receive only autologous mesenchymal stem cells. One to two million cells are spilled in the alginate bed and the medium is changed every three days until the alginate is saturated with the MSCs. Alginate will then be transplanted into the affected area. Alginate volume is determined based on the amount of damage space.

Category
Treatment - Other

2

Description
Intervention group: This group receives autologous chondrogenic pre-differentiated mesenchymal stem cells (MSCs). One to two million cells are spilled in the alginate bed and the medium is changed every three days until the alginate is saturated with the MSCs. Then we use induced media to differentiate the cells. When they induced to autologous chondrogenic pre-differentiated, the alginate containing these cells will be transplanted into the affected area. Alginate volume is determined based on the amount of damage space.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Hamadan Besat Hospital

Full name of responsible person
Dr Gholamreza Ghorbani Amjad

Street address
Department of Orthopedics, School of Medicine, Hamadan University of Medical Sciences, Hamdan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamadan University of Medical Sciences

Full name of responsible person
Dr Saeid Bashirian

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Vice Chancellor For Research And Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Blvd, Hamadan, Iran

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Hamadan

Grant name

Grant code / Reference number

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

Title of funding source
Hamadan University of Medical Sciences

Proportion provided by this source
100

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
Hamadan university of medical sciences

Full name of responsible person
Farjam Goudarzi

Position
Ph.D of Clinical Biochemistery

Other areas of specialty/work

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Other areas of specialty/work

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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