Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of autologous bone marrow stem cells in treatment of knee osteoarthritis

Protocol summary

Summary

Traumatic osteoarthritis, degenerative diseases or age-related diseases, have been controversial in terms of treatment. New methods of treatment, including stem cell transplantation in articular cartilage defects, are studied. Stem cells of the bone marrow include hematopoietic, mesenchymal and stromal stem cells. Several studies have been conducted on the use of bone marrow mononuclear cells in treatment of articular cartilage disorders. The costs of this style are less than autologous chondrocyte transplantation; that is why it is named easy one-stage style. In this study, the effect of transplantation of autologous bone marrow stem cells on pain relief and improvement of joint function was evaluated in at least 10 patients with knee osteoarthritis who had the inclusion criteria and volunteers participating in the study. IKDC evaluation form and a physical exam were done by an orthopedic collaborator. A hematology-oncology specialist obtained 30-70 ml heparinized bone marrow sample from the iliac crest. Bone marrow mononuclear cells were isolated under GMP in the clean room. After direct injection of the cells into the joint, the patients were followed by clinical examination and other evaluations including conventional radiography of the knee and knee MRI in several stages.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050922174N1**
Registration date: **2015-08-11, 1394/05/20**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-08-11, 1394/05/20

Registrant information

Name
Maryam Ayatollahi

Name of organization / entity
Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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+98 71 3628 1529

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ssci@sums.ac.ir

Recruitment status
Recruitment complete

Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2014-05-05, 1393/02/15

Expected recruitment end date
2016-05-04, 1395/02/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of autologous bone marrow stem cells in treatment of knee osteoarthritis

Public title
The effect of autologous bone marrow stem cells on knee osteoarthritis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with knee joint osteoarthritis referring to orthopedic and rehabilitation clinics, cell

therapy center of Ghadir Mother and Child hospital, and hospitals affiliated to Shiraz University of Medical Sciences. Exclusion criteria: very advanced or severe osteoarthritis; age over 65 years old; BMI greater than 25; inflammatory joint and rheumatic disease; history of cancer; chemotherapy or use of immunosuppressive drugs; diabetes; history of smoking; Knee joint laxity; varus and valgus deformity of the knee.

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **10**

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
Shiraz University of Medical Sciences

Street address
Zand Street

City
Shiraz

Postal code

Approval date
2014-02-24, 1392/12/05

Ethics committee reference number
92/429770

Health conditions studied

1

Description of health condition studied
knee osteoarthritis

ICD-10 code
m19.0

ICD-10 code description
Primary arthrosis of other joints

Primary outcomes

1

Description
Activity level function

Timepoint
3, 6, 12 month

Method of measurement
History

Secondary outcomes

1

Description
Swelling and morning stiffness

Timepoint
3, 6, 12 month

Method of measurement
History and physical exam

2

Description
Severity and frequency of pain

Timepoint
3, 6, 12 month

Method of measurement
History

3

Description
Knee locking and giving way

Timepoint
3, 6, 12 month

Method of measurement
History

4

Description
Activity level before and after injection

Timepoint
3, 6, 12 month

Method of measurement
History

Intervention groups

1

Description
Treatment by injection of stem cells

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinics Affiliated to Shiraz University of Medical Sciences, and Ghadir Mother and Child

Full name of responsible person

Street address

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

DR.Seyyed Basir Hashemi

Street address

Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Maryam Ayatollahi

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

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