

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 71 3628 1529

Email address

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

Zand Street

City

Shiraz

Postal code

Phone

+98 71 3227 9711

Fax

Email

ayatollmb@yahoo.com

Web page address

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

Street address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Maryam Ayatollahi

Position

Associate Professor, PHD in Genetics

Other areas of specialty/work

Street address

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Email

ayatollmb@yahoo.com

Web page address

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