

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of safety and feasibility of bone marrow-derived CD133 cells possesses transplantation in patients with the femoral head Osteonecrosis (AVN) -An interventional clinical trial phase I

Protocol summary

2016-10-06, 1395/07/15

Summary

Objective: Safety and efficacy assessment (such as quality of life and hip joint condition improvement and pain relief) of bone marrow derived CD133+ cell transplantation in patients with avascular necrosis of femoral head. Design: An intervention clinical trial phase I, not blinded, non randomized, uni-center in patients with avascular necrosis of femoral head. Sample size: Ten patients. Setting and conduct: Patients with osteonecrosis of the femoral head who visited in orthopedics clinic of Royan cell therapy center, would transplant autologous bone marrow derived CD133+ cells during core decompression surgery and they will follow at 2, 6 and 12 months after injection. Participants: Patients in a range of 18 to 65 years old, with femoral head osteonecrosis who are candidates for core decompression, and not suffered from other chronic diseases, viral disorders and cancer. Interventions: Implantation of autologous bone marrow derived CD133 possesses cells with core decompression procedure. Primary outcome: Safety of bone marrow derived CD133+ cell transplantation Secondary outcome: Efficacy assessment (such as quality of life and hip joint condition improvement and pain relief) of bone marrow derived CD133+ cell transplantation

Registrant information

Name

Nasser Aghdami

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell Biology and Technology, ACECR

Expected recruitment start date

2009-07-23, 1388/05/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of safety and feasibility of bone marrow-derived CD133 cells possesses transplantation in patients with the femoral head Osteonecrosis (AVN) -An interventional clinical trial phase I

Public title

Transplantation of bone marrow cells in patients with

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507231031N3**

Registration date: **2016-10-06, 1395/07/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

femoral head osteonecrosis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Upenn (Steinberg) classification of osteonecrosis, inclusive of Stages IIB and IIC that diagnosis will be based on magnetic resonance imaging (MRI); Modified index of necrotic extent < 40; Idiopathic and non-idiopathic osteonecrosis; No infection in affected bones at the time of surgery; Patient competent to give informed consent; Normal organ and marrow function defined as: Leukocytes \geq 3000/ μ L; Absolute neutrophil count \geq 1500/ μ L; Platelets \geq 140,000/ μ L; Serum AST (SGOT)/ALT (SGPT) < 2.5 X institutional standard range; Serum creatinine within normal limits, based on clinical laboratory normal range; Female patients not pregnant or lactating; Patients with a history of corticosteroids or on active therapy, will only be eligible for enrollment if corticosteroid use is suspended for 1 month prior and 6 months after cell therapy and surgery; Patients who have been treated with oral bisphosphonates are eligible for the trial if treatment was stopped at least 6 months prior to enrollment. Exclusion Criteria: Femoral head osteonecrosis' Stages IA, IB, IC, IIA, IIIA or more severe, primarily based on diagnosis by MRI; Flattening of the femur head (UPenn Stage IV) or articular cartilage collapse while core decompression surgery; Septic arthritis; stress fracture, or non-osteonecrosis metabolic bone diseases (e.g., Paget's disease of bone, osteogenesis imperfecta, primary hyperparathyroidism, fibrous dysplasia [monostotic, polyostotic McCune-Albright syndrome] and osteopetrosis); Any active bisphosphonate treatment or any history of intravenous (IV) treatment; HIV, syphilis, positive at time of screening; Active hepatitis B or hepatitis C infection at the time of screening; Known allergies to protein products (horse or bovine serum, or porcine trypsin); Patients who will require continuous, systemic, high dose corticosteroid therapy (more than 7.5 mg/day) within 6 months after surgery; received chemotherapy, radiotherapy or immunotherapy in the past 2 years; Immunodeficiency diseases; Participation in another clinical study in the past 30 days or concurrent participation in another clinical trial; History of regular alcohol consumption exceeding 2 drinks/day (1 drink = 5 oz [150 mL] of wine or 12 oz [360 mL] of beer or 1.5 oz [45 mL] of hard liquor) within 6 months of screening and/or history of illicit drug use; MRI-incompatible internal devices (pacemakers, aneurysm clips, etc); Body mass index (BMI) of 40 Kg/m² or greater; Patients unable to tolerate general anesthesia defined as an American Society of Anesthesiologists (ASA) criteria of > 2; Patients with poorly controlled diabetes mellitus (HbA1C > 8%), or with peripheral neuropathy, or known concomitant vascular problems; Patients receiving treatment with hematopoietic growth factors or anti-vasculogenesis or anti-angiogenesis treatment; Traumatic osteonecrosis

Age

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

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **10**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

1

Registry name

clinicaltrials.gov

Secondary trial Id

NCT01198080

Registration date

2010-08-09, 1389/05/18

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Royan infertility institute

Street address

Eastern Hafez St, Northern Banihashem St, Resalat highway 45 meters

City

Tehran

Postal code

Approval date

2011-05-10, 1390/02/20

Ethics committee reference number

EC/90/1028

Health conditions studied

1

Description of health condition studied

Osteonecrosis of the femoral head, unspecified

ICD-10 code

M87.9

ICD-10 code description

Osteonecrosis, unspecified

Primary outcomes

1

Description

safety of bone marrow derived CD133+ cells transplantation

Timepoint

1, 3, 6 and 12 months after transplantation

Method of measurement

MRI, Physical function, side effects

Secondary outcomes

1

Description

Quality of life

Timepoint

Before injection, 6 and 12 months after injection

Method of measurement

SF-36 Questionnaire

2

Description

Hip articular change

Timepoint

Before injection, 6 and 12 months after injection

Method of measurement

Standard WOMAC, VAS and HHS questionnaires

3

Description

Side effects

Timepoint

Before injection, 6, 12 and 24 months after injection

Method of measurement

Side effects questionnaire

Intervention groups

1

Description

Intervention group: bone marrow derived CD133+ cells injection with core compression

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinic of Royan Cell Therapy Center

Full name of responsible person

Fateme Shams

Street address

Royan Institute, Eastern Hafez St, Northern Banihashem St, Resalat highway 45 meters

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Hamid Gourabi

Street address

Eastern Hafez St, Northern Banihashem St, Resalat highway 45 meters

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Royan Institute

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

Royan Institute

Full name of responsible person

Shahedeh Karimi Torshizi

Position

M.D/ Researcher

Other areas of specialty/work

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Person responsible for scientific

inquiries

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Name of organization / entity

Royan cell Therapy Center

Full name of responsible person

Nasser Aghdami

Position

MD, PhD

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Hoda Madani

Position

researcher

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