

# 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)

##### Phone

+98 21 2356 2000

##### Email address

nasser.aghdami@royaninstitute.org

#### 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/ $\mu$ L; Absolute neutrophil count  $\geq$  1500/ $\mu$ L; Platelets  $\geq$  140,000/ $\mu$ 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/m<sup>2</sup> 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

#### City

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

#### Street address

Royan institute, Eastern Hafez St, Northern Banihashem St, 45 m Resalat highway

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#### Email

karimi58shah@gmail.com

#### Web page address

## Person responsible for scientific

## **inquiries**

### **Contact**

**Name of organization / entity**

Royan cell Therapy Center

**Full name of responsible person**

Nasser Aghdami

**Position**

MD, PhD

**Other areas of specialty/work**

**Street address**

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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*