

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Safety and Efficacy of Allogeneic Mesenchymal Stem cell Transplantation in Tibial Fractures (Closed Diaphyseal) clinical trial phase II

Protocol summary

Summary

Study object: Accelerating the tibial union and decreasing muscle weakness, joint pain and stiffness through injection of allogenic adipose derived mesenchymal stem cells. Study design: During a parallel randomized triple-blind clinical trial phase II, 40 patients with new closed tibial shaft fracture visited in Akhtar orthopedic clinics, randomly allocated to case and control groups. Setting and conduct: Placebo in the control group, and prepared allogeneic adipose-derived mesenchymal stem cells are injected in the case one, and then patients will be followed in determined times. Inclusion and exclusion criteria: Patients with 18 to 65 years old whose closed diaphyseal fracture of tibia have been proved via radiography, and are not addicted, pregnant or suffering from chronic diseases or immune deficiency, will be recruited in this study. Outcomes: Clinical and functional effects and probable adverse events following the stem cell injection will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508061031N11**

Registration date: **2017-03-15, 1395/12/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-15, 1395/12/25

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

Expected recruitment start date

2014-11-09, 1393/08/18

Expected recruitment end date

2015-06-13, 1394/03/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Safety and Efficacy of Allogeneic Mesenchymal Stem cell Transplantation in Tibial Fractures (Closed Diaphyseal) clinical trial phase II

Public title

Allogeneic Mesenchymal Stem Cell Transplantation in Tibial Closed Diaphyseal Fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age 18 to 65 years; The presence of tibial fracture based on X ray; Tibial fracture is limited to diaphysial. Exclusion Criteria: Addiction; Pregnancy; liver or kidney disease; uncontrolled diabetes; heart and lung disease; Immune deficiency.

Age

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

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

1

Registry name

ClinicalTrials.gov

Secondary trial Id

NCT02140528

Registration date

2014-05-14, 1393/02/24

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

2010-09-23, 1389/07/01

Ethics committee reference number

EC/92/1099

Health conditions studied

1

Description of health condition studied

Tibial Closed Diaphyseal Fractures

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

Primary outcomes

1

Description

Union of tibia after transplantation of mesenchymal stem cell

Timepoint

Before 3 and 6 months after injection

Method of measurement

X-ray radiography, walking distance, and whole body weight bearing by fractured limb

Secondary outcomes

1

Description

Evaluation of adverse events such as infection and edema in the fracture site

Timepoint

Before 3 and 6 months after injection

Method of measurement

Physical examination

Intervention groups

1

Description

Intervention: Single dose injection of 20 millions of allogenic adipose-derived mesenchymal stem cells into the fracture site

Category

Treatment - Drugs

2

Description

Control: Single dose injection of 3 to 5 ml normal saline into the fracture site

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Cell Therapy Center

Full name of responsible person

Fateme Shams

Street address

number 9, Shaghayegh Alley, Banihashem Sq., 45 m Resalat Highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Royan Institute

Full name of responsible person

Hamid Gourabi

Street address

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

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

City

Tehran

Postal code

Phone

00

Fax

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

M.D, Ph.D

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

+98 21 2356 2000

Fax

Email

nasser.aghdami@royaninstitute.org

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Royan Institute

Full name of responsible person

Hoda Madani

Position

Researcher/M.D

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

Phone

00

Fax

Email

hoda62_m@yahoo.com

Web page address

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