

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

evaluation of efficacy and side effects of implantation of bone marrow-derived mesenchymal stromal cells in combination with platelet lysate product in reconstruction of human nonunion of tibia fractures/a phase2 & 3 clinical trial

Protocol summary

Summary

Objectives: evaluation of effect of implantation of autologous mesenchymal stromal cells in combination with platelet lysate product, in clinical and radiological signs and symptoms relief in patients with long bone nonunion. Design: study groups and phase: two groups: case and control, phase 2& 3. Sample size: 60 patients, triple blind, randomized, single center. Setting and conduct: after autologous bone marrow aspiration, mesenchymal stromal cells will be separated and then they will be implanted into the callus site of case group in combination with platelet lysate product. For control group normal saline will be injected into the callus site. Participants: 1-patients with nonunion of tibial midshaft. 2- Fracture must be located in the middle third of the tibia. 3- Nonunion gap must be less than 1 cm. in the radiology. 4- Fracture fixed by closed intra medullary rod. 5- Patient informed the consent. 6- Atrophic type nonunion 7- 6 months last from the first operation. 8- Second procedure for nonunion has not done. Exclusion criteria: 1- infected nonunion 2- multiple major fractures. 3- Multiple major untreated fractures. Intervention: autologous bone marrow derived stromal cells implantation in patients with atrophic nonunion and normal saline as the placebo for control group. Main outcomes: primary outcomes: fracture healing in patients with nonunion. Pain relief, evaluation of walking distance. Secondary outcomes: evaluation of tumor formation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507291031N7**
Registration date: **2015-09-09, 1394/06/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-09, 1394/06/18

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

2009-02-18, 1387/11/30

Expected recruitment end date

2011-04-20, 1390/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

evaluation of efficacy and side effects of implantation of bone marrow-derived mesenchymal stromal cells in combination with platelet lysate product in

reconstruction of human nonunion of tibia fractures/a phase2 & 3 clinical trial

Public title

Reconstruction of human nonunion of tibia fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:1-patients with 18-65 years old; 2- both male & female patients; 3- patients with nonunion of tibial midshaft; 4- Fracture must be located in the middle third of the tibia; 5- Nonunion gap must be less than 1 cm. in the radiology; 6- Fracture fixed by closed intra medullary rod; 7- Patient informed the consent; 8- Atrophic type nonunion; 9- 6 months last from the first operation; 10- Second procedure for nonunion has not done. Exclusion criteria:1- infected nonunion; 2- Multiple major fractures; 3- Major untreated fracture; 4- History of cancer; 5- Allergy to protein or other cell culture medium gradients; 6- Uncontrolled chronic diseases; 7- Need to steroid usage in the period of treatment; 8- Positive for HIV or other viral diseases; 9- Pregnant or lactating women; 10- Include in other trail

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

no other feature

Secondary Ids

1

Registry name

ClinicalTrials.gov

Secondary trial Id

NCT01206179

Registration date

empty

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

2015-01-13, 1393/10/23

Ethics committee reference number

EC/93/1100

Health conditions studied

1

Description of health condition studied

Disorders of continuity of bone

ICD-10 code

M84.1

ICD-10 code description

Nonunion of fracture [pseudarthrosis]

Primary outcomes

1

Description

bone fusion

Timepoint

3 months after injection

Method of measurement

before and after injection radiology photographs

Secondary outcomes

1

Description

pain

Timepoint

1-3- 6-12 months after injection

Method of measurement

VAS

2

Description

Tumor formation in contrast with placebo group

Timepoint

1-3-6-12 months

Method of measurement

graphy

3

Description

walking distance

Timepoint

1-3- 6-12 months after injection

Method of measurement

Questionnaire

Intervention groups**1****Description**

Control group: implantation of normal saline as the placebo into the nonunion site.

Category

Treatment - Drugs

2**Description**

Intervention group: Stromal cell therapy: by using autologous bone marrow derived stromal cells. After bone marrow aspiration, mesenchymal stromal cells will be separated and then they will be implanted to the nonunion site under the guide of fluoroscopy.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akhtar Hospital

Full name of responsible person

Mohammadreza Abbasian

Street address

Next to Ayatollah Taleghani Hospital, Shahid A'rabi Avenue, Yaman Avenue, Shahid Chamran Highway, Tehran

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell

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

Department of Regenerative Biomedicine, Cell Science Research Center, Royan Institute for Stem Cell

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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Royan Institute

Full name of responsible person

Nasser Aghdami

Position

MD, PhD

Other areas of specialty/work**Street address**

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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

Other areas of specialty/work**Street address**

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

City

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Phone

00

Fax

Email

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