# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Oct 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 out comes: 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**
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## Person responsible for updating data

**Contact**
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**Full name of responsible person**
Hoda Madani
**Position**
researcher
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00
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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*