Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
Street address
Eastern Hafez St,Northern Banihashem St, Resalat highway 45 meters
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
Other areas of specialty/work
Street address
Royan institute, Eastern Hafez St,Northern Banihashem St, Resalat highway 45 meters
City
Tehran
Postal code

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