

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of intramyocardial transplantation of autologous bone marrow derived MNC (MonoNuclear Cell) and CD133+ cells comparison to placebo, on LVEF in MI patients, A Phase II/III, Multicenter, Placebo-Controlled, Randomized, Double-Blind Clinical Trial

Protocol summary

Summary

Objectives: improvement of left ventricular function in STEMI patients after intramyocardial injections of 2 types of autologous bone marrow derived cells into the infarcted myocardium compared to a placebo group during CABG. Design: A Phase II/III, Multicenter, Placebo-Controlled, Randomized, Double-Blind Clinical Trial
Methods: 90 patients with first anterior STEMI (10 days - 3 months), 18-75 years, both gender and CABG candidate selected for randomization in 3 groups [CD133+, the MNC (MonoNuclear Cell), and placebo] and intramyocardial injection during CABG. They underwent real or sham aspiration. They followed at 6 and 18 months after surgery by SPECT and clinical assessments. The primary endpoint was assessed by changes in global left ventricular ejection fraction (LVEF) at rest by gated SPECT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612201031N20**

Registration date: **2017-01-14, 1395/10/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-14, 1395/10/25

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

2007-12-31, 1386/10/10

Expected recruitment end date

2012-06-30, 1391/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intramyocardial transplantation of autologous bone marrow derived MNC (MonoNuclear Cell) and CD133+ cells comparison to placebo, on LVEF in MI patients, A Phase II/III, Multicenter, Placebo-Controlled, Randomized, Double-Blind Clinical Trial

Public title

Intramyocardial injection of transplantation of autologous bone marrow derived MNC (MonoNuclear Cell) and CD133+ cells comparison to placebo, on LVEF in MI patients

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: 18-75 years; First ST elevation myocardial infarction (STEMI) 10 days - 3 months; Post-acute myocardial infarction (AMI) left ventricular ejection fraction (LVEF) as assessed by echocardiography: 20%-45%; Target lesion must be located in the left anterior descending (LAD) section; Coronary artery bypass graft (CABG) candidate; At least 4 akinetic segments (assessed by stress echocardiography).
 Exclusion criteria: History of prior AMI; Active infection; History of recurrent infection; Positive test for syphilis (RPR); Hepatitis B and C (HBsAg, anti-HBc, anti-HCV); HIV or HTLV-1; Documented terminal illness or malignancy; Documented autoimmune disease; Pulmonary edema; Urgent or emergency CABG; Systolic blood pressure <80 mmHg; 4000 > leukocytes (μL) >15000; AST >100 IU/L or ALT >100 IU/L; Hemoglobin <10 g/dL; Platelets <100,000/μL; INR >1.8

Age
 From **18 years** old to **75 years** old

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **90**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features
 Computer-generated randomization sequence in a 1:1:1 ratio between the CD133+, the MNC, and placebo groups

Secondary Ids

1

Registry name
 ClinicalTrials.gov

Secondary trial Id
 NCT01167751

Registration date
 2010-07-19, 1389/04/28

Ethics committees

1

Ethics committee
Name of ethics committee
 Ethics committee of Royan infertility institute

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

City
 Tehran

Postal code

Approval date
 2006-10-04, 1385/07/12

Ethics committee reference number
 106-85-پ

Health conditions studied

1

Description of health condition studied
 Acute transmural myocardial infarction of anterior wall

ICD-10 code
 I21.0

ICD-10 code description
 Transmural infarction (acute)(of): • anterior (wall) NOS • anteroapical • anterolateral • anteroseptal

Primary outcomes

1

Description
 Changes in global left ventricular ejection fraction (LVEF) at rest between group

Timepoint
 Base, 6 and 18 months after CABG

Method of measurement
 SPECT

Secondary outcomes

1

Description
 NYHA classification

Timepoint
 base and 18 month after CABG

Method of measurement
 Standard classification of NYHA

2

Description
 Perfusion defect score (PDS)

Timepoint
 Base, 6 and 18 months after CABG

Method of measurement
 SPECT

3

Description
 Non-viable (NV) segments

Timepoint
 Base, 6 and 18 months after CABG

Method of measurement

SPECT

4

Description

Decrease systolic wall thickening (Dec. Thickening) of the myocardium

Timepoint

Base, 6 and 18 months after CABG

Method of measurement

SPECT

5

Description

Wall motion score (WMS)

Timepoint

Base, 6 and 18 months after CABG

Method of measurement

SPECT

6

Description

Adverse events assessment (included death, reinfarction, implantable cardioverter defibrillator (ICD) placement, infection, and arrhythmia)

Timepoint

Base, 6 and 18 months after CABG

Method of measurement

Physician assessment

Intervention groups

1

Description

Intervention: Intramyocardial injection of 3 cc autologous bone marrow derived cell (MNC) using a 22-gauge needle

Category

Treatment - Other

2

Description

Intervention: Intramyocardial injection of 3 cc autologous bone marrow derived cell (CD133) using a 22-gauge needle

Category

Treatment - Other

3

Description

Intervention: Intramyocardial injection of 3 cc placebo using a 22-gauge needle

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital

Full name of responsible person

Dr. Mohammad Hassan Naseri

Street address

Molasadra St., Chamran Highway

City

Tehran

2

Recruitment center

Name of recruitment center

Shahid Dr. Lavasani Hospital

Full name of responsible person

Dr. Hossein Hosseinejad

Street address

Tehransar

City

Tehran

3

Recruitment center

Name of recruitment center

Tehran Heart Center Hospital

Full name of responsible person

Dr.Hossein Ahmadi

Street address

North Karegar St.

City

Tehran

4

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center

Full name of responsible person

Dr.Saeed Hosseini

Street address

Niyayesh ave crossroad, valiasr st.

City

Tehran

5

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Dr.Zargham Ahmadi

Street address

Darabad, Bahonar St.

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, 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

Hoda Madani

Position

M.D/ Researcher

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

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

City

Tehran

Postal code**Phone**

+98 21 2356 2458

Fax**Email**

hoda62_m@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Royan Institute

Full name of responsible person

Nasser Aghdami

Position

M.D/Ph.D

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

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**

Eastern Hafez St,Northern Banihashem St, 45 m
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City

Tehran

Postal code**Phone**

+98 21 2356 2458

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