

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

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5

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Dr.Zargham Ahmadi

Street address

Darabad, Bahonar St.

City

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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

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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

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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