

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The efficacy of intramyocardial injection of bone marrow-derived mesenchymal and CD133+ stem cells on improvement of cardiac ejection fraction in patients undergoing CABG in Shariati Hospital

Protocol summary

Summary

Main Objective: Assessment of the efficacy of intramyocardial injection of bone marrow-derived mesenchymal and CD133+ stem cells on improvement of cardiac Ejection Fraction (EF) in patients undergoing Coronary Artery Bypass Surgery (CABG). This Study will be carried out as a clinical trial without control group, enrolling 9 patients considering inclusion and exclusion criteria. After selection of patients and taking informed consent from them and completing necessary tests and stress echocardiography and scintigraphy Radio-nucleotide Scan, a sample of bone marrow is taken to prepare mesenchymal and CD133+ cell. At the time of open heart surgery, 1ml of prepared cells is injected into myocardium around the scar. Patients are followed with physical examination, stress echocardiography and scintigraphy Radio-nucleotide Scan in 1 and 6 months after CABG.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902113799N2**
Registration date: **2010-05-26, 1389/03/05**
Registration timing: **na**

Last update:

Update count: **0**

Registration date

2010-05-26, 1389/03/05

Registrant information

Name

Nasim Shayan

Name of organization / entity

Cardiac Transplantation Research Center (CTRC)

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Iran (Islamic Republic of)

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Recruitment status

Not enough for processing

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-09-01, 1390/06/10

Expected recruitment end date

2009-03-19, 1387/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The efficacy of intramyocardial injection of bone marrow-derived mesenchymal and CD133+ stem cells on improvement of cardiac ejection fraction in patients undergoing CABG in Shariati Hospital

Public title

The efficacy of intramyocardial injection of bone marrow-derived mesenchymal and CD133+ stem cells on improvement of cardiac ejection fraction in patients undergoing CABG in Shariati Hospital

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1- Candidate for Coronary Artery Bypass Surgery (CABG) 2- History of Myocardial Infarction in 2-12 weeks ago 3- Age: 30-70 years 4-

Ejection Fraction (EF) < %40 in Doppler
Echocardiography 5- Presence of Akinesia in Doppler
Echocardiography 6- Informed Consentience for this
research Exclusion Criteria: 1- Age < 30 yrs. or >70 yrs.
2- Unsuitable for Coronary Artery Bypass Surgery (CABG)
3- Patients with severe co-morbidity or history of open
heart surgery 4- Absence of Scar in Scintigraphy Radio-
nucleotide Scan 5- Patient in cardiac shock or needs for
emergency heart surgery 6- Patient with moderate to
severe valvular disease 7- In-consentience for this
research

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **9**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

DDRC Ethics Committee

Street address

Shariati Hospital

City

Tehran

Postal code

Approval date

2009-03-01, 1387/12/11

Ethics committee reference number

FWA00001331; DHHS-IRB00001641

Health conditions studied

1

Description of health condition studied

Chronic ischemic heart Disease

ICD-10 code

I25.2

ICD-10 code description

Myocardial Infarction

Primary outcomes

1

Description

Cardiac Scan Findings

Timepoint

before and 6 months after Surgery

Method of measurement

scintigraphy Radio-nucleotide Scan

2

Description

Functional Class

Timepoint

before and 1 & 6 months after Surgery

Method of measurement

Medical History and physical examination

3

Description

Ejection Fraction (EF)

Timepoint

before and 6 months after Surgery

Method of measurement

Stress Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Injection of Stem cell in Myocard

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr Mohammad Rezaei

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Laleh Hospital

Full name of responsible person

Dr MohammadReza MohammadHasani

Street address**City**

Tehran

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

Technology cooperation office of Persidency

Full name of responsible person

Dr Seyed Majid Manavi

Street address

No. 9, Golha Blvd., Sattarkhan Ave.

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Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Technology cooperation office of Persidency

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**

Cardiac Transplantation Research Center (CTRC)

Full name of responsible person

Mohammad Rezaei MD

Position

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Cardiac Transplantation Research Center (CTRC)

Full name of responsible person

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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