

# 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)

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8863 3037

##### Email address

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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.

**City**

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**

CTRC Research Supervisor / MD

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Cardiac Transplantation Research Center (CTRC)

**Full name of responsible person**

Mohammadreza Mohammadhasani MD

**Position**

Assistant professor of Cardiology

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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*