

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluating the safety of autologous intra papillary muscle injection of bone marrow stem cell in patients with up to moderate ischemic mitral regurgitation: A Phase II clinical trial

Protocol summary

Summary

Ischemic mitral regurgitation (IMR) is a common complication after myocardial infarction (MI), following more frequently an inferior MI (38%) rather than anterior ones (10%). Moreover, the management of mild to moderate IMR at the time of coronary artery bypass graft surgery (CABG) is controversial, and its impact on clinical outcomes is still unclear. In addition to medical therapy and surgical or interventional revascularization strategies, intramyocardial stem cell therapy has become a new therapeutic option for patients with end-stage ischemic heart disease. Moreover, it has been shown that in the chronic post-infarction setting, autologous skeletal myoblast transplantation attenuates mild to moderate chronic ischemic MR, which is otherwise progressive, by decreasing tethering distance over which the leaflets are stretched and improving ejection fraction and wall motion score, thereby enhancing valve coaptation. These promising preclinical results led to several clinical trials evaluating possible benefits of stem cell transplantation in humans. Since apical or posterior displacement of the papillary muscle (PM) in inferior MI results in perturbation of the MV complex and tethering of the MV leaflets, using stem cell therapy would be a practical alternative in mitral regurgitation. Given the limitations of existing methods for repairing ischemic MR in patients, we are on this supposition that direct intra papillary muscle injection of bone marrow stem cells (BMSCs) in ischemic posteromedial PM in up to moderate IMR in addition to CABG would improve the functional parameters of such patients. 30 patients from Dr. Ghavidel surgery service who meet the inclusion criteria at Rajaei heart center are included in this Phase II clinical trial. All patients are first time candidates for cardiac surgery. They will be randomized into two equal groups with Random number table method of randomization Treatment: All patients

will undergo conventional multivessel CABG (complete revascularization). We will inject 10 times (each 0.2 ml per single injection and each 0.5 to 1 X MNC cells per single injection) targeting the infarction border zone. A swab is used to occlude the injection channel for several seconds to minimize reflux of cell suspension. Immediately after the cell injection, de-airing and atrial grafts are done and all proximal grafts will be finalized and the aortic clamp was removed, and the operation was completed as usual. Control group: All patients will undergo conventional multivessel CABG (complete revascularization)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201308138860N5**

Registration date: **2013-08-23, 1392/06/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-08-23, 1392/06/01

Registrant information

Name

Alireza Alizadeh Ghavidel

Name of organization / entity

Rajaei Heart Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 2147

Email address

aghavidel@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source
Rajaei Heart Center

Expected recruitment start date
2013-12-22, 1392/10/01

Expected recruitment end date
2014-12-22, 1393/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the safety of autologous intra papillary muscle injection of bone marrow stem cell in patients with up to moderate ischemic mitral regurgitation: A Phase II clinical trial

Public title
A new technique by intra papillary muscle injection of autologous bone marrow stem cell in patients with up to moderate ischemic mitral regurgitation

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1. Recent posterior-inferior MI* (≥ 2 weeks but ≤ 2 months) 2. Planned complete Revascularization, 3. No evidence of myocardial viability in the infarct area of PM, as shown by a preoperative low-dose dobutamine echocardiography. (Akinetic or dyskinetic segments seen on echocardiography, and lack of myocardial viability on dobutamine echocardiography) 4. Up to moderate Ischemic Mitral Regurgitation 5. LVEF ≥ 25 % Exclusion criteria: 1. Previous myocardial revascularization; 2. Not complete revascularization during CABG 3. Left ventricular aneurysm; 4. Permanent or persistent ventricular arrhythmias; 5. Severe valvular disease; 6. History of any hematological disease, including leucopenia (≤ 3.000 white cells/ μL), thrombocytopenia (≤ 120.000 platelets/ μL), or thrombocytosis (≥ 450.000 platelets/ μL); 7. Hepatic or renal dysfunction (serum creatinine ≥ 2 mg/mL, ALT ≥ 2 times of normal value); 8. Positive history of HIV 9. Evidence of malignant diseases or unwillingness to participate.

Age
From **18 years** old

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Junction of Shahid Hemmat and Shahid Chamran expressways

City

Tehran

Postal code

Approval date

2013-06-19, 1392/03/29

Ethics committee reference number

92-01-14-17081-86439

Health conditions studied

1

Description of health condition studied

Mitral (valve) insufficiency

ICD-10 code

I34.0

ICD-10 code description

Mitral (valve) insufficiency

Primary outcomes

1

Description

Mortality

Timepoint

12 months

Method of measurement

ID

Secondary outcomes

1

Description

Arrhythmia

Timepoint

40 days, 6 and 12 months after release

Method of measurement

ECG holter

2

Description

Papillary muscles viability

Timepoint

6 month after surgery

Method of measurement

Cardiac MRI

3

Description

Cardiac Enzymes

Timepoint

Every 6 hours during admission in the hospital

Method of measurement

Laboratory kit

4

Description

CRP

Timepoint

During admission, 40 days, 6 and 12 months after release

Method of measurement

Laboratory kit

5

Description

Wall motion Score Index

Timepoint

During admission, 6 and 12 months after release

Method of measurement

Transthoracic Echocardiography

6

Description

MR Severity

Timepoint

During admission, 6 and 12 months after release

Method of measurement

Transthoracic Echocardiography

7

Description

MRSV

Timepoint

During admission, 6 and 12 months after release

Method of measurement

Transthoracic Echocardiography

8

Description

Iso Volumic Relaxation Time (IVRT

Timepoint

During admission, 6 and 12 months after release

Method of measurement

Transthoracic Echocardiography

9

Description

Chamber Relaxation velocity)/(Myocard relaxation velocity) (E/e)

Timepoint

During admission, 6 and 12 months after release

Method of measurement

Transthoracic Echocardiography

10

Description

(IVRT/(QE-Qe

Timepoint

During admission, 6 and 12 months after release

Method of measurement

Transthoracic Echocardiography

11

Description

Left ventricular ejection fraction

Timepoint

During admission, 6 and 12 months after release

Method of measurement

Transthoracic Echocardiography

Intervention groups

1

Description

Treatment: All patients will undergo conventional multivessel CABG (complete revascularization). We will inject 10 times (each 0.2 ml per single injection and each 0.5 to 1 X MNC cells per single injection) targeting the infarction border zone. A swab is used to occlude the injection channel for several seconds to minimize reflux of cell suspension

Category

Treatment - Surgery

2

Description

Control group: All patients will undergo conventional multivessel CABG (complete revascularization)

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Heart Center

Full name of responsible person

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Rajaie cardiovascular medical and research center
Full name of responsible person
Dr. Majid Haghjoo
Street address
Valiasr Ave. Nyayesh Blvd.
City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rajaie cardiovascular medical and research center

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
Rajaie heart center
Full name of responsible person
Dr. Alireza Alizadeh Ghavidel
Position
Associate Professor
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Person responsible for scientific inquiries

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Person responsible for updating data

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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