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 Rajaee 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 (each0.2 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 (each0.2 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
Other areas of specialty/work
Street address
Valiasr Ave, Nyayesh Blvd
City
Tehran
Postal code
Phone
+98 21 2392 2147
Fax
Email
AAghavidel@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rajaie Heart Center
Full name of responsible person
Dr. Alireza Alizadeh Ghavidel
Position
Associate Professor
Other areas of specialty/work
Street address
Valiasr Ave, Nyayesh Blvd.
City
Tehran
Postal code
Phone
+98 21 2392 2147
Fax
Email
AAghavidel@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Rajaie Heart Center
Full name of responsible person
Dr. Alireza Alizadeh Ghavidel
Position
Associate Professor
Other areas of specialty/work
Street address
Valiasr Ave, Nyayesh Blvd.
City
Tehran
Postal code
Phone
+98 21 2392 2147
Fax
Email
AAghavidel@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