Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of aortic root injection of adenosine on myocardial protection in patients undergoing coronary artery bypass surgery

Protocol summary

Summary

Objective: To investigate the effect of aortic root injection of adenosine on myocardial protection in patients undergoing coronary artery bypass graft surgery Study design: double blinded randomized clinical trial. Inclusion Criteria All CAD patients candidate for coronary artery bypass surgery(CABG) in Shiraz hospitals; completing the consent form for participation in the study. Exclusion criteria: Ejection Fraction less than 40%; over 70 years of age; using a balloon pump (IABP); receiving preoperative inotrope; redo –surgeries; combined surgery; emergency surgery; pulmonary disease; chronic atrial fibrillation; chronic arrhythmia treatment. Methods: 52 patients are divided into two groups of 26patients. After sternotomy and grafting , cannulation is performed. Aorta is clamped, 12 mg adenosine is injected through the cardiopulmonary cannula and cold blood cardioplegia solution with antigrad method will be injected. And in the control group (B), they receive the same amount of placebo before the injection of the cardioplegia solution. The cardiac immobilization time from the onset of cardioplegia solution injection to cardiac asystol will be recorded. After aortic declamping, we record the momentum of the beat of the heart. Arterial blood samples are taken for determining the serum level of CPK-MB enzymes, troponin I, at the induction of anesthesia 6, 12, and 24 hours after surgery. Arrhythmia, type and dose of inotropes, homodynamic changes (systolic and diastolic pressure, mean arterial pressure) heart rate, and mechanical ventilation time at 6 and 24 hours after surgery will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017013019470N51**

Registration date: **2017-08-08, 1396/05/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-08, 1396/05/17

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4270

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research , Shiraz University of Medical Sciences

Expected recruitment start date

2017-08-02, 1396/05/11

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of aortic root injection of adenosine on myocardial protection in patients undergoing coronary artery bypass surgery

Public title

The effect of aortic root injection of adenosine on myocardial protection in patients undergoing coronary artery bypass surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion Criteria All CAD patients candidate for coronary artery bypass surgery(CABG) in Shiraz hospitals; completing the consent form for participation in the study. Exclusion criteria: Ejection Fraction less than 40%; over 70 years of age; using a balloon pump (IABP); receiving preoperative inotrope; redo –surgeries; combined surgery; emergency surgery; pulmonary disease; chronic atrial fibrillation; chronic arrhythmia treatment.

Age
To **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **52**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City
Shiraz

Postal code

Approval date
2016-09-25, 1395/07/04

Ethics committee reference number
IR.SUMS.REC.1395.116

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Surgery

ICD-10 code
125.1

ICD-10 code description
Atherosclerotic heart disease

Primary outcomes

1

Description
the serum level of CPK-MB enzymes, troponin I

Timepoint
at the induction of anesthesia 6, 12, and 24 hours after surgery

Method of measurement
Arterial blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 12 mg adenosine is injected through the cardiopulmonary cannula and cold blood cardioplegia solution with antigrad method will be injected.

Category
Treatment - Drugs

2

Description
control group: Patients will be taken 5 cc normal saline before the injection of the cardioplegia solution.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hoptioal

Full name of responsible person
Behrooz Moslemi

Street address
Namazi Hoptioal, Namazi Square

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Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Shiraz University of Medical Sciences
Full name of responsible person
Dr Seed Basir Hashemi
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Shiraz University of Medical Sciences
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

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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