Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Esmolol before cardioplegia and in the cardioplegic solution on the myocardial injury biomarkers in coronary artery bypass graft surgery patients

Protocol summary

Study aim
Use of esmolol in the cardioplegic solution for reducing myocardial injury in patients with CABG
Design
randomized double-blinded placebo-controled clinical trial
Settings and conduct
Chamran Heart Complex of Isfahan Univerdsity of Medical Sciences
Participants/Inclusion and exclusion criteria
Having surgery just by coronary artery bypass Left ventricular Ejection fraction between 45-60% Left ventricle end-diastole Diameter (LVEDD) less than 60 mm
Intervention groups
esmolol in the cardioplegic solution for the intervention group and the routine cardioplegic solution for the control group.
Main outcome variables
Faster healing in patients undergoing cardiac surgery

General information

Reason for update
The trial protocol has been updated due to the investigator's wishes in order to improve the quality of trial design and conduction methodology.
Acronym
IRCT registration information
IRCT registration number: **IRCT20180428039456N1**
Registration date: **2019-07-26, 1398/05/04**
Registration timing: **prospective**

Last update: **2021-03-26, 1400/01/06**
Update count: **3**
Registration date
2019-07-26, 1398/05/04

Registrant information
Name
Ehsan Rangraz
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-03-03, 1397/12/12
Expected recruitment end date
2020-05-03, 1399/02/14
Actual recruitment start date
2019-08-01, 1398/05/10
Actual recruitment end date
2020-09-30, 1399/07/09
Trial completion date
2020-10-30, 1399/08/09

Scientific title
The effect of Esmolol before cardioplegia and in the cardioplegic solution on the myocardial injury biomarkers in coronary artery bypass graft surgery patients

Public title
The effect of Esmolol before cardioplegia and as a combination in cardioplegia on biochemical markers of myocardial injury in patients undergoing coronary artery bypass graft surgery
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:

Only coronary bypass grafting surgery candidates due to coronary artery disease and atherosclerosis Left ventricular Ejection fraction between 45-60% Left ventricle end diastole Diameter (LVEDD) less than 60 mm Age above 18 years old Not having diabetes mellitus type 2 or consuming any oral hypoglycemic agents Not having severe systemic diseases (including any pulmonary, hepatic, renal, and musculoskeletal diseases or immune system illnesses) Not participating in any other studies Not having any confirmed arrhythmia or consuming any anti-arrhythmic agents (except beta-blockers)

Exclusion criteria:

Not willing to participate in the study No need for emergency operation No history of inappropriate reaction to Esmolol Not received Esmolol over the past 30 days

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **280**

Actual sample size reached: **280**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients are allocated into either the intervention or control group using a non-stratified block randomization method to keep an even randomization ratio of (1:1). Random Allocation Software is used by our expert analytics to determine the list and group of patients. He is blinded to the selection process and pre- and post-operative assessments. The block size will be equal and is set to 4, the sufficient and estimated sample size will be 280, then the allocation code is set to sequential. The analytics will use the output of software to determine the sequence and allocation of patients. Then each code is written on a non-transparent envelope and a paper is put in it in which the intervention or control is written on the paper. The series of the envelope will be according to the software's list and they will keep in a large box with a locker. The analytics has the key for the box and this box will be kept in his room which the analytics has its only key and has no windows. As the patients enrolled in the study sequentially, the analytics use the designated envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

All of the involved investigators and researchers, participants, principle surgeon, technician of cardiopulmonary bypass machine, anesthesiologist, and other operation room staff will not know which A or B is intervention or placebo group. Only the pharaceutical company which manufacture the ampule which is contaning the active drug or steril normal saline knows that.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of isfahan university of Medical sciences

Street address

Hezar jerib Ave,isfahan university of Medical sciences

City

isfahan

Province

Isfehan

Postal code

7346181746

Approval date

2019-03-03, 1397/12/12

Ethics committee reference number

IR.MUI.MED.REC.1397.290

Health conditions studied

1

Description of health condition studied

coronary Artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Average of cardiac biomarkers Troponin I, CK-MB and LDH

Timepoint

Measurement of biochemical markers of myocardial injury before and 4, 12, 24 and 48 hours after surgery

Method of measurement

Patient blood samples and laboratory measurements

Secondary outcomes

1

Description
Frequency of ventricular fibrillation during the heart re-beat
Timepoint
After unclamping the aorta
Method of measurement
Electrocardiogram

2

Description
hours of ICU stay
Timepoint
After the surgery
Method of measurement
hours documented in the charts

3

Description
Duration of patient admission after surgery in hospital
Timepoint
Number of hospital admission days in the post-operative
Method of measurement
Follow patient

4

Description
Need for inotropic drugs
Timepoint
Check the number of inotropes used
Method of measurement
Follow patient

Intervention groups

1

Description
The intervention group receives esmolol hydrochloride (as 100 mg/10 ml vial, ESOCARD, SAMARTH life sciences PVT. LTD pharmaceutical Co. INDIA) during the operation. First, as a 2 mg/kg in central venous catheter just before starting the CPB. After 5 minutes, the patient will put on CPB. Half of the first dose (1 mg/kg) will then be infused with the cardioplegic solution after aortic cross-clamping. This dose will be repeated for the next doses of the cardioplegic solution during the surgery.
Category
Treatment - Drugs

2

Description
Control group: The control group received the same volume of normal saline (10 mL) from an exact vial (manufactured in the Afachemi Pharmaceutical Co. IRAN).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran hospital
Full name of responsible person
Ehsan Rangraz
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available