

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 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-controlled clinical trial

Settings and conduct

Chamran Heart Complex of Isfahan University 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

Country

Iran (Islamic Republic of)

Phone

+98 31 3521 1312

Email address

ehsanrangraz@yahoo.com

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 pharmaceutical company which manufacture the ampule which is containing 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

Isfahan

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

Street address

Chamran Hospital, Salman farsi Ave , Isfahan

City

Isfahan

Province

Isfahan

Postal code

8156166764

Phone

+98 31 3260 0961

Email

EhsanRangraz@yahoo.COM

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ehsan Rangraz

Street address

Isfahan univ.medical science Azadi

City

Isfahan

Province

Isfahan

Postal code

8156166764

Phone

+98 31 3521 1312

Email

EhsanRangraz@yahoo.com

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

+98 31 3260 0961

Email

drshahzamani@yahoo.com

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehran Shahzamani

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Chamran Hospital, Salman farsi Ave , Isfahan

City

isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3260 0961

Email

drshahzamani@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Ehsan Rangraz

Position

Master of science

Latest degree

Master

Other areas of specialty/work

Cardiology

Street address

Chamran Hospital, Salman farsi Ave , Isfahan

City

Isfahan

Province

Isfahan

Postal code

8156166764

Phone

+98 31 3524 3409

Email

Ehsanrangraz@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mehran Shahzamani

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

Street address

Chamran Hospital, Salman farsi Ave , Isfahan

City

Isfahan

Province

Isfahan

Postal code

7346181746

Phone

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