

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison study of continuous infusion and bolus of Esmolol on hemodynamic response to laryngoscopy and endotracheal intubation in coronary artery bypass graft patients

Protocol summary

Study aim

Comparison of continuous infusion and bolus Esmolol on hemodynamic responses to laryngoscopy and endotracheal intubation in patients undergoing CABG surgery

Design

Randomized, double blind, phase 3 clinical trial on 66 patients

Settings and conduct

According to the criteria, after obtaining written consent, patients are randomly divided into study groups including: infusion group, bolus group and control group. Preoperative medical treatment continues until the morning of surgery. Age, sex, weight, height, chronic disease and medications are recorded. After entering the operating room, patients are monitored by pulse oximeter, electrocardiogram and non-invasive blood pressure. To monitor blood pressure invasively, an intra-arterial catheter is inserted into the left radial artery after local injection of Lidocaine. Patients are intubated 3 minutes after induction of general anesthesia. HR and systolic blood pressure and diastolic blood pressure and mean blood pressure before infusion to induction, during and after induction of anesthesia, at laryngoscopy and endotracheal intubation and every minute for 10 minutes after endotracheal intubation are recorded.

Participants/Inclusion and exclusion criteria

Patients candidated for CABG elective surgery with ASA 2-4 and EF > 40%.

Intervention groups

Infusion group: 0.5 mg/kg Esmolol is injected within 4 minutes and then the infusion is started at 200 µg/kg/min and continues until endotracheal intubation. 0.9% NaCl is administered 2 minutes before endotracheal intubation. Bolus group: 1.5mg/kg Esmolol is administered as a venous bolus 2 minutes before intubation and 0.9 NaCl% is administered 10 minutes

before endotracheal intubation until it. Control group: 0.9% NaCl infusion and bolus of normal saline are given instead of Esmolol.

Main outcome variables

Heart rate, systolic blood pressure, diastolic blood pressure, mean blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200822048478N2**

Registration date: **2020-10-04, 1399/07/13**

Registration timing: **retrospective**

Last update: **2020-10-04, 1399/07/13**

Update count: **0**

Registration date

2020-10-04, 1399/07/13

Registrant information

Name

mohammad tobeiha

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5554 0021

Email address

tobeiha-m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2017-03-20, 1395/12/30
Actual recruitment start date
2015-07-23, 1394/05/01
Actual recruitment end date
2017-07-21, 1396/04/30
Trial completion date
2018-08-21, 1397/05/30

Scientific title

Comparison study of continuous infusion and bolus of Esmolol on hemodynamic response to laryngoscopy and endotracheal intubation in coronary artery bypass graft patients

Public title

Continuous infusion of Esmolol in patients undergoing CABG surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ASA 2-4 undergoing elective CABG surgery EF>40%

Exclusion criteria:

AV conduction block greater than grade 1 asthma acute MI HR<50 Mallampati score greater than 2 Kidney or liver failure History of allergy or Idiosyncratic reaction to β -blockers Systolic blood pressure less than 100 mmHg Diastolic blood pressure less than 50 mmHg

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

We are going to randomize based on Permuted block randomization method. In this way, all 6 groups of 3 groups (20 blocks) are determined and using the random number table, the number of blocks is selected and a sequence of groups A, B and c is determined and each patient is based on the entry number. The plot is placed in one of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

After consciously agreeing to participate in the study, patients are randomly assigned to one of three study groups. researchers, evaluators of the outcome, and data Analyzer don't know about which patient is in which One of the treatment groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

5th of Qotb -e Ravandi Blvd. P.O.Box: 8715988141, Kashan, IRAN

City

Kashan

Province

Isfahan

Postal code

8715988141

Approval date

2015-05-24, 1394/03/03

Ethics committee reference number

IR.KAUMS.REC.1394.19

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

heart rate

Timepoint

HR and systolic blood pressure and diastolic blood pressure and mean blood pressure before infusion to induction, during and after induction of anesthesia, at laryngoscopy and endotracheal intubation and every minute for 10 minutes after endotracheal intubation are recorded.

Method of measurement

After entering the operating room, patients are monitored by pulse oximeter, electrocardiogram and non-invasive blood pressure.To monitor blood pressure invasively, an intra-arterial catheter is inserted into the left radial artery after local injection of Lidocaine.

2

Description

systolic blood pressure

Timepoint

HR and systolic blood pressure and diastolic blood pressure and mean blood pressure before infusion to induction, during and after induction of anesthesia, at laryngoscopy and endotracheal intubation and every minute for 10 minutes after endotracheal intubation are recorded.

Method of measurement

After entering the operating room, patients are monitored by pulse oximeter, electrocardiogram and non-invasive blood pressure. To monitor blood pressure invasively, an intra-arterial catheter is inserted into the left radial artery after local injection of Lidocaine.

3

Description

diastolic blood pressure

Timepoint

HR and systolic blood pressure and diastolic blood pressure and mean blood pressure before infusion to induction, during and after induction of anesthesia, at laryngoscopy and endotracheal intubation and every minute for 10 minutes after endotracheal intubation are recorded.

Method of measurement

After entering the operating room, patients are monitored by pulse oximeter, electrocardiogram and non-invasive blood pressure. To monitor blood pressure invasively, an intra-arterial catheter is inserted into the left radial artery after local injection of Lidocaine.

4

Description

mean blood pressure

Timepoint

HR and systolic blood pressure and diastolic blood pressure and mean blood pressure before infusion to induction, during and after induction of anesthesia, at laryngoscopy and endotracheal intubation and every minute for 10 minutes after endotracheal intubation are recorded.

Method of measurement

After entering the operating room, patients are monitored by pulse oximeter, electrocardiogram and non-invasive blood pressure. To monitor blood pressure invasively, an intra-arterial catheter is inserted into the left radial artery after local injection of Lidocaine.

Secondary outcomes

empty

Intervention groups

1

Description

Infusion group: 0.5 mg/kg Esmolol is injected within 4 minutes and then the infusion is started at 200 µg/kg/min and continues until endotracheal intubation. 0.9% NaCl is administered 2 minutes before endotracheal intubation. Esmolol is manufactured by Claris company, India.

Category

Treatment - Drugs

2

Description

Bolus group: 1.5mg/kg Esmolol is administered as a venous bolus 2 minutes before intubation and 0.9 NaCl% is administered 10 minutes before endotracheal intubation until it. Esmolol is manufactured by Claris company, India.

Category

Treatment - Drugs

3

Description

Control group: 0.9% NaCl infusion and bolus of normal saline are given instead of Esmolol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Mohammadreza Sharif

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beheshtihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafshe

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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

Kashan 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

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hosein Akbari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hosein Akbari

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biostatistics

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mohammad Tobeiha

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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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