Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 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)

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+98 31 5554 0021

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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

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Province

Isfehan

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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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Position
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Other areas of specialty/work
Biostatistics

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Person responsible for updating data

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Full name of responsible person
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Medical student

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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