

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the Hemodynamic Changes of three regimens propofol, diazepam and etomidate during anesthesia induction in low EF CABG patients

Protocol summary

Summary

Researchers have always been investigating to produce methods and drugs with least hemodynamic changes occur during induction of anesthesia and laryngoscopy in patients. Propofol and Etomidate are well-known anesthetic agents routinely used for the induction of anesthesia for cardiac surgeries. The two drugs however have different induction characteristics. Etomidate is only unique drug with standard doses for induction of anesthesia and laryngoscopy, hemodynamic changes were not observed in patients. Despite the great advantage of lack of hemodynamic changes during anesthesia induction, Etomidate can cause inhibition of cortisol production in response to ACTH and can increase morbidity and mortality in these patients. Considering the importance and effectiveness of hemodynamic changes resulting in surgical procedures and mortality related to it and the results contradict previous studies, we need to investigate in a study to compare the propofol, diazepam and etomidate for induction of anesthesia with the least hemodynamic changes in patients with low ejection fraction. The aim of the present study is to compare the hemodynamic responses of etomidate, propofol and diazepam during anesthesia induction, laryngoscopy and tracheal intubation in CABG surgery patients with low EF in order to find proper drug establishing more stable hemodynamic. Methods: it is double blind randomized, clinical study will be conducted for total 150 patients with low ejection fraction undergoing coronary artery bypass graft surgery. Preliminary selection of patients will be randomly. Inclusion criteria is patients with CAD and left ventricular dysfunction (EF < 35%), stable hemodynamic (SBP > 90), scheduled for elective CABG surgery with CPB and no fatal dysrhythmias. Exclusion criteria included known adrenal insufficiency, chronic inflammatory diseases, history of steroid use in the preceding six months,

endocrine or neurological illnesses, tracheal intubation time more than 30 seconds, sepsis, endocarditis, combined cardiac valve surgery with CABG and Bentall surgery. After approval from the institutional ethics committee and written informed consent from the patients, a total of 150 patients will be included in this study and will randomly allocated to group A and B and C (50 patients in each group) by the sealed envelope technique. Patient allocation will be performed by a nurse who was unaware of the study groups, according to numbers generated by the computer generated list. In the operating room and before induction of anesthesia, 5 cc/kg Ringer lactate will be infused for all patients via an intravenous line. Also electrocardiogram, invasive arterial blood pressure, and pulse oximeter will applied for all patients and baseline systolic and diastolic arterial blood pressure (SAP, DAP), mean arterial pressure (MAP) and heart rate (HR) will be measured and recorded for all of them. Then all patients will receive fentanyl (2 µg/kg) and midazolam (0.03 mg/kg) intravenously as premedication. One minute later, patients in group A will induced with propofol (1.5 mg/kg), group B Etomidate (0.2 mg/kg) and group C Diazepam (0.3 mg/kg). All drugs will receive the drugs at the same speed and within 60-90 seconds. Then, all patients will receive 1.5 mg/kg succinylcholine for muscle relaxation to facilitate intubation. One minute after succinylcholine administration, tracheal intubation will be performed. Hemodynamic variables including SAP, DAP, MAP and HR will measured immediately before and after laryngoscopy and intubation, one, two and three minutes after intubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082921669N2**
Registration date: **2016-07-22, 1395/05/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-22, 1395/05/01

Registrant information

Name

Aria Soleimani

Name of organization / entity

Mazandaran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Fatemeh Zahra Hospital

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2015-04-14, 1394/01/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Hemodynamic Changes of three regimens propofol,diazepam and etomidate during anesthesia induction in low EF CABG patients

Public title

Comparison of the Hemodynamic Changes of three regimens propofol,diazepam and etomidate during anesthesia induction in low EF CABG patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1- elective surgery. 2- aged 35_80 years old. 3- Ejection fraction (EF<35%). 4- Elective CABG surgery with CPB. Exclusion criteria : 1-adrenal insufficiency 2- history of steroid use in the preceding six months 3-sepsis,endocarditis,chronic inflammatory diseases 4,5-combined cardiac valve surgery with CABG and Bentall surgery. 6-tracheal intubation time more than 30 seconds

Age

From **35 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

student research committee of mazandaran university of medical sciences

Street address

Moallem square

City

Sari

Postal code

Approval date

2014-01-21, 1392/11/01

Ethics committee reference number

278

Health conditions studied

1

Description of health condition studied

General anesthesia for patients with cardiac disease

ICD-10 code

I50.1

ICD-10 code description

Left ventricular failure

Primary outcomes

1

Description

systolic and diastolic Blood pressure

Timepoint

During intervention

Method of measurement

sphygmomanometer/IBP

2

Description

Heart Rate

Timepoint

During intervention

Method of measurement

monitoring

3

Description

Mean arterial pressure

Timepoint

During intervention

Method of measurement

IBP

4

Description

Ejection fraction

Timepoint

One day before intervention

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Laryngoscopy duration

Timepoint

One minute after intubation

Method of measurement

Coronometer

2

Description

Weight

Timepoint

One day before intervention

Method of measurement

Document

Intervention groups

1

Description

Eomidate 0.2 mg Hypnotic agent

Category

Treatment - Drugs

2

Description

Propofol 1.5 mg/kg Hypnotic agent

Category

Treatment - Drugs

3

Description

Diazepam 0.3 mg/kg Hypnotic agent

Category

Treatment - Drugs

4

Description

Midazolam 0.03 mg/kg as premedication 1 minute before induction of anesthesia

Category

Treatment - Drugs

5

Description

Fentanyl (2µg/kg) as premedication drug 1 minutes before induction of anesthesia

Category

Treatment - Drugs

6

Description

Succinylcholine 1.5 mg/kg as muscle relaxation one minute after hypnotic drug administration

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemeh Zahra hospital

Full name of responsible person

Street address

Fatemeh Zahra hospital, Shahr-dari square, Artesh Blvd

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Mazandaran University of Medical Sciences

Full name of responsible person

Student Research Committee

Street address

Moallem square

City

Sari

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 and Technology of
Mazandaran 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

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Neda Heidari

Position

Bachelors degree in Anesthesia

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

Aria Soleimani

Position

Fellowship of cardiac anesthesia/Assistant professor

Other areas of specialty/work

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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