Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 dysrhytmias . 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 (2µg/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 (0.3mg/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
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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
Documemt

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 relaxationone 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, Shahrdari 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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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