Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effect of midazolam, etomidate and propofol on hemodynamic changes in patients undergoing coronary artery bypass graft surgery: a double -blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of midazolam, etomidate and propofol on hemodynamic changes in patients undergoing coronary artery bypass graft surgery

Design
This is a double-blind randomized clinical trial, in which 90 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct
The eligible patients who are candidate for coronary artery bypass graft surgery referring to the Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double -blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age of 40 to 70 years, Candidate for coronary artery bypass graft surgery, Exclusion criteria: Diabetes, Requires emergency coronary artery bypass graft surgery

Intervention groups
Intervention group 1: Intravenous infusion of midazolam (manufactured by Oxir Pharmaceutical Co.) 0.15 mg/kg single dose before anesthesia Intervention group 2: Intravenous infusion of etomidate (manufactured by Abureihan Pharmaceutical Co.) 0.2 mg/kg single dose before anesthesia Intervention group 3: Intravenous infusion of propofol (manufactured by Tehran Shimi Pharmaceutical Co.) 1.5 mg/kg single dose before anesthesia

Main outcome variables
Primary outcome: Heart rate, systolic and diastolic blood pressure, mean arterial blood pressure, electrocardiographic changes

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N391**
Registration date: **2021-04-23, 1400/02/03**
Registration timing: **prospective**

Last update: **2021-04-23, 1400/02/03**
Update count: **0**

Registration date
2021-04-23, 1400/02/03

Registrant information

Name
Jalal Poorolajal

Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-11-21, 1400/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of midazolam, etomidate and propofol on hemodynamic changes in patients undergoing coronary artery bypass graft surgery: a double -blind randomized clinical trial

Public title
Comparison of the effect of three medications on clinical symptoms of patients undergoing open heart surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age of 40 to 70 years, Candidate for coronary artery bypass graft surgery,
Exclusion criteria:
Diabetes, Requires emergency coronary artery bypass graft surgery

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on two sheets the name of the intervention 1 and on two other sheets the name of the intervention 2 and on the third two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all six sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The shape of the medications will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Hamadan University of Medical Sciences

Street address
Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences, Shahid Fahmideh Ave

City
Hamadan

Province
Hamadan

Postal code
6517838695

Approval date
2021-04-10, 1400/01/21

Ethics committee reference number
IR.UMSHA.REC.1400.072

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft surgery

ICD-10 code
I25.709

ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s), unspecified, with unspecified angina pectoris

Primary outcomes

1

Description
Heart rate

Timepoint
One minute before induction of anesthesia and at 1, 2, 5 and 10 minutes after intubation

Method of measurement
Using monitoring machine

2

Description
Systolic blood pressure

Timepoint
One minute before induction of anesthesia and at 1, 2, 5 and 10 minutes after intubation

Method of measurement
Using monitoring machine

3

Description
Mean arterial blood pressure
Timepoint
One minute before induction of anesthesia and at 1, 2, 5 and 10 minutes after intubation
Method of measurement
Using monitoring machine

4

Description
Electrocardiographic changes
Timepoint
One minute before induction of anesthesia and at 1, 2, 5 and 10 minutes after intubation
Method of measurement
Using monitoring machine

5

Description
Diastolic blood pressure
Timepoint
One minute before induction of anesthesia and at 1, 2, 5 and 10 minutes after intubation
Method of measurement
Using monitoring machine

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Intravenous infusion of midazolam (manufactured by Oxir Pharmaceutical Co.) 0.15 mg/kg single dose before anesthesia
Category
Treatment - Drugs

2

Description
Intervention group 2: Intravenous infusion of etomidate (manufactured by Abureihan Pharmaceutical Co.) 0.2 mg/kg single dose before anesthesia
Category
Treatment - Drugs

3

Description
Intervention group 3: Intravenous infusion of propofol (manufactured by Tehran Shimi Pharmaceutical Co.) 1.5 mg/kg single dose before anesthesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Farshchian Heart Hospital in Hamadan city
Full name of responsible person
Parsa Afghanian
Street address
Farshchian Heart Hospital, Shahid Fahmideh Ave.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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
Hamedan 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
Hamedan University of Medical Sciences

Full name of responsible person
Parsa Afghanian

Position
Medical Student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Position
Anesthesiologist

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Medical doctor

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Anesthesiology

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Person responsible for updating data

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Professor of Epidemiology

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Ph.D.

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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