Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

Comparison of the Hemodynamic Changes of two regimens propofol + ketamin and thiopental Na + ketamin with etomidate during anesthesia induction

Protocol summary

Summary

The aim of this randomized double-blind clinical trial is to evaluate and comparison the hemodynamic changes of two regimens propofol + ketamine and thiopental Na + ketamine with etomidate during anesthesia induction. A total of 120 patients, meeting eligibility criteria, were randomly allocated into three equal groups. Inclusion criteria are informed written consent; ASA class I-II; Age between 18 and 45 years; Elective surgery. Exclusion criteria are Adrenal insufficiency; Received etomidate or propofol or thiopental in one week ago; Receiving steroids at 6 months ago; Sensitivity to etomidate or propofol or thiopental; Egg and soy allergy; Sepsis; endocarditis; Chronic inflammatory diseases; Any severe disease and seriously endocrine, neurological, Psychiatric and Metabolic disorders; Pregnant or lactating women; Need for rapid intubation in emergency patients; Asthma; HIV infection; History of hypertension; Taking beta blocker, calcium blockers and angiotensin II inhibitors. After establishing routine monitors, blood pressure (systole, diastole and mean arterial pressure) and heart rate are measured and serve as baseline values. At first, all patients will receive 0.02 mg/kg midazolam and 2 µg/kg fentanyl. One minute later anesthesia induces according to the following regimen; group A: Normal saline + 0.3 mg/kg Etomidate, group B: 0.5 mg/kg Ketamine + 1.5 mg/kg Propofol, group C: 0.5 mg/kg Ketamine + 3 mg/kg thiopental Na. Immediately after the prescribed hypnotic drug, 1.5 mg/kg succinylcholine for muscle relaxation and ease of intubation will be used. 1 min after administration of hypnotic drugs just before laryngoscopy as well as 1 and 3 min after laryngoscopy and tracheal intubation, blood pressure and heart rate will be measured and compared in three groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103114365N7**
Registration date: **2011-07-10, 1390/04/19**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-07-10, 1390/04/19

Registrant information

Name
Afshin Gholipour Baradari
Name of organization / entity
Mazandaran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Expected recruitment start date

2011-04-04, 1390/01/15

Expected recruitment end date

2011-07-06, 1390/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the Hemodynamic Changes of two regimens propofol + ketamin and thiopental Na + ketamin with etomidate during anesthesia induction

Public title
Comparison of the Hemodynamic Changes of two regimens propofol + ketamin and thiopental Na + ketamin with etomidate during anesthesia induction

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Informed written consent; ASA class I-II; Age between 18 and 45 years; Elective surgery
Exclusion criteria: Adrenal insufficiency; Received etomidate or propofol or thiopental in one week ago; Receiving steroids at 6 months ago; Sensitivity to etomidate or propofol or thiopental; Egg and soy allergy; Sepsis; endocarditis; Chronic inflammatory diseases; Any severe disease and seriously endocrine, neurological, Psychiatric and Metabolic disorders; Pregnant or lactating women; Need for rapid intubation in emergency patients; Asthma; HIV infection; History of hypertension; Taking beta blocker, calcium blockers and angiotensin II inhibitors.

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

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
Ethics committee of Mazandaran University of Medical Sciences

Street address
Mazandaran University of Medical Sciences, Moallem Square

City
Sari

Postal code
46175866

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
89-185

Health conditions studied

1

Description of health condition studied
Hemodynamic Change

ICD-10 code
197.9

ICD-10 code description
Postprocedural disorder of circulatory system, unspecified

Primary outcomes

1

Description
Systolic blood pressure

Timepoint
1 min after administration of hypnotic drugs just before laryngoscopy as well as 1 and 3 min after laryngoscopy and tracheal intubation

Method of measurement
Automated sphygmomanometer

2

Description
Diastolic blood pressure

Timepoint
1 min after administration of hypnotic drugs just before laryngoscopy as well as 1 and 3 min after laryngoscopy and tracheal intubation

Method of measurement
automated sphygmomanometer

3

Description
Mean arterial pressure

Timepoint
1 min after administration of hypnotic drugs just before laryngoscopy as well as 1 and 3 min after laryngoscopy and tracheal intubation

Method of measurement
automated sphygmomanometer

4

Description

Heart rate

Timepoint

1 min after administration of hypnotic drugs just before laryngoscopy as well as 1 and 3 min after laryngoscopy and tracheal intubation

Method of measurement

Heart monitoring

Secondary outcomes

1

Description

Delirium

Timepoint

After anesthesia

Method of measurement

Inspection

2

Description

Nausea and vomiting

Timepoint

After anesthesia

Method of measurement

Inspection

3

Description

twitching

Timepoint

After anesthetic infusion

Method of measurement

Inspection

4

Description

pain

Timepoint

After anesthetic infusion

Method of measurement

Inspection

Intervention groups

1

Description

Control group: Normal saline + 0.3 mg/kg Etomidate

Category

Treatment - Drugs

2

Description

Intervention group 1 : 0.5 mg/kg Ketamine + 1.5 mg/kg Propofol

Category

Treatment - Drugs

3

Description

Intervention group 2 : 0.5 mg/kg Ketamine + 3 mg/kg thiopental Na

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini General Hospital

Full name of responsible person

Afshin Gholipour Baradari, MD

Street address

Imam Khomeini general Hospital, Amir St.

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati MD

Street address

Mazandaran university of medical sciences, Moallem Square, Sari, Iran

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 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

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Afshin Gholipour Baradari MD
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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