

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3326 1245

##### Email address

gholipourafshin@mazums.ac.ir

##### 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

**Full name of responsible person**

Afshin Gholipour Baradari MD

**Position**

CCMF, Assistant Professor, Chief of ICU

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**Full name of responsible person**

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**Position**

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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*