

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

21 Jun 2026

### Comparison of the effect of propofol plus ketamine with propofol plus etomidate on hemodynamic stability during induction of anesthesia in elderly patients candidate for elective surgeries

#### Protocol summary

##### Summary

Our aim in this study is to compare the effect of propofol plus ketamine with propofol plus etomidate on hemodynamic stability during induction of anesthesia in elderly patients candidate for elective surgeries. Key inclusion criteria are to have indication for elective surgeries and to be 50 or over 50 years old. Key exclusion criteria are pregnancy and to have contraindication for etomidate, ketamine and propofol. 60 eligible males and females candidate for surgery in Emam Reza hospital, Tabriz would be studied in two groups of 30. In the group Ketofol, ketamine 0.75 mg/kg and propofol 1 mg/kg would be administered intra-venously to induce the anesthesia. In addition, Ketamine 0.25 mg/kg and propofol 1 mg/kg would be prepared to be administered as a second dose in case of patient agitation. In the group Etofol, etomidate 0.2 mg/kg and propofol 1 mg/kg will be administered intra-venously to induce the anesthesia. In addition, Etomidate 0.1 mg/kg and propofol 1 mg/kg would be prepared to be administered as a second dose in case of patient agitation. Systolic and diastolic blood pressure, mean arterial blood pressure, heart rate and blood O<sub>2</sub> saturation would be measured before and immediately after induction, 1 and 3 minutes after intubation. And then, the results would be compared.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112224731N10**

Registration date: **2012-01-01, 1390/10/11**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-01-01, 1390/10/11

##### Registrant information

###### Name

Hamze Hosseinzade

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1334 7055

###### Email address

hosseinz@tbzmed.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Tabriz University of Medical Sciences

##### Expected recruitment start date

2011-04-21, 1390/02/01

##### Expected recruitment end date

2012-04-19, 1391/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of propofol plus ketamine with propofol plus etomidate on hemodynamic stability during induction of anesthesia in elderly patients candidate for elective surgeries

##### Public title

propofol with ketamine or propofol with etomidate, which one influences the hemodynamic stability lesser?

## Purpose

Supportive

## Inclusion/Exclusion criteria

Inclusion criteria: to have indication for elective surgeries; to be 50 or over 50 years old. Exclusion criteria: to have indication for emergency surgery; addiction to opiate; pregnancy; patients being treated with sedative or antipsychotic drugs in the past month; to have a personality disorder; to have body weight more than 20% of the ideal body weight for that height and gender; to have contraindication for etomidate, ketamine and propofol

## Age

From **50 years** old to **149 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

N/A

## 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 Tabriz University of Medical Sciences

##### Street address

Daneshgah square

##### City

Tabriz

##### Postal code

#### Approval date

2011-07-25, 1390/05/03

#### Ethics committee reference number

9059

## Health conditions studied

### 1

#### Description of health condition studied

Change in heart rate caused by anesthesia induction

#### ICD-10 code

R00.1

#### ICD-10 code description

Bradycardia, unspecified

### 2

#### Description of health condition studied

Change in blood pressure caused by anesthesia induction

#### ICD-10 code

I95.9

#### ICD-10 code description

Hypotension, unspecified

## Primary outcomes

### 1

#### Description

Systolic blood pressure

#### Timepoint

Before and immediately after induction, 1 and 3 minutes after intubation

#### Method of measurement

Non-invasive monitoring device with automatic cuff

### 2

#### Description

Heart rate

#### Timepoint

before and immediately after induction, 1 and 3 minutes after intubation

#### Method of measurement

Continuous ECG monitoring

### 3

#### Description

Blood O2 saturation

#### Timepoint

before and immediately after induction, 1 and 3 minutes after intubation

#### Method of measurement

pulse oximetry

### 4

#### Description

Diastolic blood pressure

#### Timepoint

before and immediately after induction, 1 and 3 minutes after intubation

#### Method of measurement

Non-invasive monitoring device with automatic cuff

### 5

#### Description

Mean arterial blood pressure

#### Timepoint

before and immediately after induction, 1 and 3 minutes after intubation

**Method of measurement**

non-invasive monitoring devices with automatic cuff

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

In the group Ketofol, ketamine 0.75 mg/kg and propofol 1 mg/kg would be administered intra-venously to induct the anesthesia. Plus, Ketamine 0.25 mg/kg and propofol 1 mg/kg would be prepared to be administered as a second dose in case of patient agitation.

**Category**

Prevention

**2**

**Description**

In the group Etofol, etomidate 0.2 mg/kg and propofol 1 mg/kg will be administered intra-venously to induct the anesthesia. Plus, Etomidate 0.1 mg/kg and propofol 1 mg/kg would be prepared to be administered as a second dose in case of patient agitation.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam Reza hospital

**Full name of responsible person**

Hamzeh Hosseinzadeh

**Street address**

Emam Reza hospital, Golgasht street

**City**

Tabriz

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Hamzeh Hosseinzadeh

**Street address**

Emam Reza hospital, Golgasht street

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahmoud Vasebi

**Position**

Anesthesiology resident, student

**Other areas of specialty/work**

**Street address**

Emam Reza hospital, Golgasht street

**City**

Tabriz

**Postal code**

**Phone**

+98 41 1335 7314

**Fax**

**Email**

vasebim@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mahmoud Vasebi

**Position**

Anesthesiology resident, student

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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## Web page address

## 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*