

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 O₂ 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

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vasebim@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mahmoud Vasebi

Position

Anesthesiology resident, student

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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Position

Anesthesiology resident, student

Other areas of specialty/work**Street address**

Emam Reza hospital, Golgasht street

City

Tabriz

Postal code**Phone****Fax****Email**

vasebim@yahoo.com

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