

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Comparing the effect of three methods for induction of anesthesia (propofol, Etomidate, propofol+Etomidate) on quality of laryngeal mask airway replacement and hemodynamic stability in elective surgeries

Protocol summary

Summary

The purpose of this randomized clinical trial is to compare the effects of three methods of anesthesia induction (propofol, etomidate and propofol+etomidate) on quality of laryngeal mask airway replacement and hemodynamic stability in elective surgeries. A total of 90 patients with ASA I and II class, undergoing elective surgeries, will be randomly allocated into one of the following three groups. Before anesthesia induction all patients will receive %0.9 Normal saline 6 mL/kg. Thirty minutes before anesthesia induction, all patients were premedicated using fentanyl 2microg/kg + midazolam 0.025 mg/kg +lidocaine 1mg/kg intravenously (IV). Interventions in this clinical trial are: propofol Propofol 2.5 mg/kg, or Etomidate Etomidate 0.3 mg/kg, or propofol and Etomidate Etomidate 0.2 mg/kg plus propofol 1 mg/kg which will be given once to induce anesthesia required for surgery. Heart rate, systolic blood pressure, diastolic blood pressure, mean arterial pressure and pulse oximetry are measured before induction and 30 seconds after induction. Laryngeal masks are inserted by a blind investigator 60 seconds after anesthesia induction. Apnea time is recorded in all patients. The correct placement of LMA was verified using capnography, chest movement and absence of leakage around the cuff. Later, anesthesia is maintained using oxygen (3 L/min), nitrous oxide (3 L/min), and isoflurane(1-1.5%).The reactions from the patients are also graded. If LMA insertion is unsuccessful and patient had coughing, gagging or movement of head or limbs, the patients receive an additional dose in all three groups. In group one: propofol 0.5 mg/kg, group two: etomidate 0.15 mg/kg and group three: propofol 0.25 mg/kg plus etomidate 0.1mg/kg.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101054731N5**

Registration date: **2012-01-15, 1390/10/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-01-15, 1390/10/25

Registrant information

Name

Hamze Hosseinzade

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research vice-chancellor of 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

Comparing the effect of three methods for induction of anesthesia (propofol, Etomidate, propofol+Etomidate) on quality of laryngeal mask airway replacement and hemodynamic stability in elective surgeries

Public title

propofol, etomidate or propofol with etomidate which one influences quality of laryngeal mask replacement and hemodynamic stability lesser.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Adult patients with ASA (American society of Anesthesiologist) class I and II; age between 18-70 years; undergoing surgery with LMA (Laryngeal Mask Airway). Exclusion criteria: Pharynx or larynx pathology; mouth opening less than 2cm; bronchial asthma; cardiovascular diseases or mallampati 3-4.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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**

Research vice-chancellor of Tabriz university of medical sciences

Street address

Golghasht

City

Tabriz

Postal code**Approval date**

2011-04-04, 1390/01/15

Ethics committee reference number

5/4/2793

Health conditions studied**1****Description of health condition studied**

1:Heart rate changes due to induction of anesthesia

ICD-10 code

R00.1

ICD-10 code description

Bradycardia,unspecified

2**Description of health condition studied**

Blood pressure changes due to induction of aneesthesia

ICD-10 code

R03.1

ICD-10 code description

Nonspecific low blood-pressure reading

Primary outcomes**1****Description**

Systolic blood pressure

Timepoint

Before anesthesia,after induction of anesthesia,before insertion of LMA, after insertion LMA and every 1min up to 3min

Method of measurement

non invesive monitoring devices with automatic cuff

2**Description**

Dyastolic blood pressure

Timepoint

Before anesthesia,after induction of anesthesia,before insertion of LMA, after insertion LMA and every 1min up to 3min

Method of measurement

non invesive monitoring devices with automatic cuff

3**Description**

Mean arterial pressure

Timepoint

Before anesthesia,after induction of anesthesia,before insertion of LMA, after insertion LMA and every 1min up to 3min

Method of measurement

non invesive monitoring devices with automatic cuff

4**Description**

Heart rate

Timepoint

Before anesthesia,after induction of anesthesia,before insertion of LMA ,after insertion LMA and every 1min up to 3min

Method of measurement

continuos ECG monitoring

5

Description

Oxygen saturation

Timepoint

Before anesthesia,after induction of anesthesia,before insertion of LMA ,after insertion LMA and every 1min up to 3min

Method of measurement

Pulse oxymetry devices

6

Description

The apnea time after induction anesthesia until return of the first spotaneos ventilation

Timepoint

Before anesthesia,after induction of anesthesia,before insertion of LMA ,after insertion LMA and every 1min up to 3min

Method of measurement

continuos ECG monitoring

Secondary outcomes

1

Description

Quality of laryngeal mask airway replacement

Timepoint

After replacement larygeal mask airway

Method of measurement

Insertion condition were graded in a system modifid from lund and stovener

2

Description

Number of attempts for LMA insetion

Timepoint

Number of attempt

Method of measurement

observation

3

Description

Quality of airway

Timepoint

After replacement larygeal mask airway

Method of measurement

observation

Intervention groups

1

Description

Propofol 2.5mg/kg will be given once to put the patient to sleep for surgery

Category

Prevention

2

Description

Etomidate 0.3mg/kg will be given once to put the patient to sleep for surgery

Category

Prevention

3

Description

Propofol 1mg/kg plus Etomidate 0.2 mg/kg will be given once to put the patient to sleep for surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Hosseinzade Hamze

Street address

Golgasht street

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice-chancellor of Tabriz university of medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

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City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research vice-chancellor of 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

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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