

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of the effect of induction of anesthesia by Propofol or Thiopental sodium or Etomidate on hemodynamic changes during microlaryngeal surgery

#### Protocol summary

##### Summary

This study was aimed to analyze the effect of three drugs (Propofol, Etomidate and Thiopental sodium) in hemodynamic changes during suspension laryngoscopy as hypnotic drugs. This is a double-blinded study on 75 patients undergoing elective suspension laryngoscopy. Inclusion criteria are: ASA (American Society of Anesthesiologists) I and II classes; 17 - 80 years old patients undergoing elective suspension laryngoscopy without history of hypertension; no history of cerebrovascular accidents; no history of acute porphyria; no food allergy (specially to soya and egg). Exclusion criteria are: airway obstruction; laryngospasm; need to re-intubation after laryngoscope excitation; systolic blood pressure less than 90 mmHg at fifth minute and surgery duration more than 30 minutes. Patients were divided into three groups of Etomidate (received 0.3 mg/kg), Propofol (received 2.2 mg/kg) and Thiopental sodium (received 5 mg/kg) and hemodynamic parameters at 1, 3, 5, 10, 15 minutes after induction and 3, 5, 15, 30 minutes after recovery, surgeon's satisfaction of surgery, surgery duration and recovery time were measured. We understood that there is no difference between administration of Propofol, Etomidate and Thiopental sodium in terms of hemodynamic changes, surgeon's satisfaction of anesthesia and surgery duration.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015030421327N1**

Registration date: **2015-04-25, 1394/02/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-04-25, 1394/02/05

##### Registrant information

###### Name

Leila Karshenas

###### Name of organization / entity

Isfahan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3668 0048

###### Email address

m-manoochehri@pel.iaun.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2013-01-20, 1391/11/01

##### Expected recruitment end date

2014-03-16, 1392/12/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of induction of anesthesia by Propofol or Thiopental sodium or Etomidate on hemodynamic changes during microlaryngeal surgery

##### Public title

Comparison of the induction of anesthesia by Propofol or Thiopental sodium or Etomidate during microlaryngeal

surgery

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: age of 17-80; American Society of Anesthesiologist (ASA) I and II classes; no history of hypertension; no history of cerebrovascular accidents; no food allergy (especially to soya and egg); no history of acute porphyria Exclusion criteria: air way obstruction; laryngospasm; need to re-intubation after laryngoscope excitation; systolic blood pressure five minutes after induction of anesthesia less than 90 mmHg; surgery duration more than 30 minutes

## Age

From **17 years** old to **80 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **75**

## 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

Isfahan University of Medical Sciences

##### Street address

Isfahan University of Medical Sciences, Hezar jarib St.

##### City

Isfahan

##### Postal code

#### Approval date

2013-01-09, 1391/10/20

#### Ethics committee reference number

391459

## Health conditions studied

### 1

#### Description of health condition studied

General anesthasia

## ICD-10 code

T88.5

## ICD-10 code description

Other complications of anaesthesia

## Primary outcomes

### 1

#### Description

Diastolic blood pressure

#### Timepoint

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

#### Method of measurement

mm-Hg, sphygmomanometer

### 2

#### Description

Systolic blood pressure

#### Timepoint

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

#### Method of measurement

mm-Hg, sphygmomanometer

### 3

#### Description

Heart rate

#### Timepoint

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

#### Method of measurement

Electrocardiogram monitor

### 4

#### Description

O2 saturation

#### Timepoint

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

#### Method of measurement

Pulseoxymeter

### 5

#### Description

Surgeon's satisfaction of surgery

#### Timepoint

After the surgery

#### Method of measurement

Questionnaire

## 6

### **Description**

Time of surgery

### **Timepoint**

Operation's time duration

### **Method of measurement**

Timer

## 7

### **Description**

Time of recovery hospitalization

### **Timepoint**

Recovery duration

### **Method of measurement**

Timer

## 8

### **Description**

Mean arterial pressure

### **Timepoint**

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

### **Method of measurement**

mm-Hg, sphygmomanometer

## **Secondary outcomes**

### 1

#### **Description**

Hypotension

#### **Timepoint**

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

#### **Method of measurement**

mm-Hg, sphygmomanometer

### 2

#### **Description**

Tachycardia

#### **Timepoint**

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

#### **Method of measurement**

Electrocardiogram monitor

### 3

#### **Description**

Hypertension

#### **Timepoint**

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

#### **Method of measurement**

mm-Hg, sphygmomanometer

## 4

### **Description**

Bradycardia

### **Timepoint**

Before and during intervention and after recovery time.  
1, 3, 5, 10, 15 min after drug injection and 3, 5, 15, 30 min after recovery

### **Method of measurement**

Electrocardiogram monitor

## **Intervention groups**

### 1

#### **Description**

Propofol, 2.2 mg/kg within 30 seconds; IV.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Thiopental sodium, 5 mg/kg within 30 seconds; IV.

#### **Category**

Treatment - Drugs

### 3

#### **Description**

Etomidate, 0.3 mg/kg within 30 seconds; IV.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Alzahra Hospital

##### **Full name of responsible person**

Dr Mehrdad Masoudifar

##### **Street address**

Alzahra Hospital, Softe Blv, Isfahan, Iran

##### **City**

Isfahan

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Ayatollah Kashani Hospital

##### **Full name of responsible person**

Dr Mehrdad Masoudifar

##### **Street address**

Ayatollah Kashani Hospital, Ayatollah Kashani St.

##### **City**

Isfahan

## **Sponsors / Funding sources**

## 1

### Sponsor

**Name of organization / entity**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Mehrdad Masoudifar

**Street address**

Isfahan University of Medical Sciences, Hezar jarib St.

**City**

Isfahan

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Isfahan 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**

Isfahan University of Medical Sciences

**Full name of responsible person**

Dr Mehrdad Masoudifar

**Position**

Assistant professor

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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Leila Karshenas

**Position**

Medical student

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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*