

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of thiopental sodium-midazolam combination on hemodynamic response to tracheal intubation and laryngeal mask insertion

Protocol summary

Study aim

The aim of this study was to evaluate the effect of thiopental sodium-midazolam combination on hemodynamic responses to tracheal intubation or laryngeal airway mask insertion.

Design

Single blind randomized clinical trial, the total sample size is 70

Settings and conduct

After confirmation by the Ethics Committee of Isfahan University of Medical Sciences, this randomized, single blind randomized clinical trial study was performed on 70 ASA-1,2 patients in the age group of 35 to 75 years who are candidates for short-term surgical procedures under general anesthesia. Patients are divided in two groups of 35 by using Random Allocation software in 2 groups airway administrations with ETT and LMA. Finally, the effect of thiopental sodium and midazolam on hemodynamic variables in two groups will be investigated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing elective short-term surgery (less than two hours) Age of 35 to 75 years ASA I-II Exclusion criteria: Obese patients Pregnant women Diabetic patients COPD patients Cardiovascular patients predict difficult airway protection Any allergies to used anesthetic drugs

Intervention groups

Group 1: Airway Administration with ETT. Group 2: Airway Administration with LMA

Main outcome variables

Heart rate Systolic blood pressure Diastolic blood pressure Median arterial blood pressure O2 saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039326N6**

Registration date: **2019-02-02, 1397/11/13**

Registration timing: **retrospective**

Last update: **2019-02-02, 1397/11/13**

Update count: **0**

Registration date

2019-02-02, 1397/11/13

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-29, 1397/10/08

Expected recruitment end date

2019-01-10, 1397/10/20

Actual recruitment start date

2018-12-29, 1397/10/08

Actual recruitment end date

2019-01-10, 1397/10/20

Trial completion date

2019-01-10, 1397/10/20

Scientific title

The effect of thiopental sodium-midazolam combination on hemodynamic response to tracheal intubation and laryngeal mask insertion

Public title

Effect of Thiopental Sodium - Midazolam on the hemodynamic response to the tracheal intubation and laryngeal mask insertion

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients undergoing elective short-term surgery less than two hours Age of 35 to 75 years and ASA I-II Informed consent to Participate in the Study

Exclusion criteria:

Obese patients Pregnant women Diabetic patients COPD patients Cardiovascular patients predict difficult airway management History of allergy to used anesthetic drugs

Age

From **35 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Actual sample size reached: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients who met the criteria for entering the study randomly using random numbers generated by the computer assign to group E (Tracheal intubation) and group L (laryngeal mask-insertion), the Patient allocation was performed by an independent researcher, who was unaware of the study groups, Sequence numbers in the sealed black envelope were kept in an inaccessible location, at the end of the study, these numbers list were available for data analysis

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the patient will not be aware of the airway management and the information will be obtained single blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical

Sciences

Street address

Isfahan University of medical sciences, Hezar Jarib Street

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Province

Isfahan

Postal code

8174673461

Approval date

2018-12-29, 1397/10/08

Ethics committee reference number

IR.MUI.MED.REC.1397.182

Health conditions studied

1

Description of health condition studied

Hemodynamic response

ICD-10 code

T88.5

ICD-10 code description

Other complications of anaesthesia

Primary outcomes

1

Description

Heart rate

Timepoint

Basic time, minutes 1 and 3 after induction and minutes 1, 3, 5 and 10 after intubation

Method of measurement

Electrocardiogram (EKG)

2

Description

Blood pressure

Timepoint

Basic time, minutes 1 and 3 after induction and minutes 1, 3, 5 and 10 after intubation

Method of measurement

Pressure gauge

3

Description

Mean arterial pressure

Timepoint

Basic time, minutes 1 and 3 after induction and minutes 1, 3, 5 and 10 after intubation

Method of measurement

Pressure gauge

4

Description

Oxygen saturation percentage

Timepoint

Basic time, minutes 1 and 3 after induction and minutes 1, 3, 5 and 10 after intubation

Method of measurement

Pulse oximetry

Secondary outcomes

empty

Intervention groups

1

Description

First intervention group: After receiving 5 ml / kg of ringer lactate and pre-oxygenation for patients, the same anesthetic induction was performed including Fentanyl 2mcg / kg, Thiopental sodium 2.5 mg / kg, Midazolam 0.1 mg/kg and Atracurium 0.5 mg / kg, and the patients underwent mechanical ventilation by mask for three minutes. Then the airway is protected by ETT and the patient is attached to the anesthetic machine and is mechanically ventilated and maintained anesthetized with iso-fluorine 0.8-1.2 Mac, with oxygen and N2O of 50%.

Category

Treatment - Drugs

2

Description

First intervention group: After receiving 5 ml / kg of ringer lactate and pre-oxygenation for patients, the same anesthetic induction was performed including Fentanyl 2mcg / kg, Thiopental sodium 2.5 mg / kg, Midazolam 0.1 mg/kg and Atracurium 0.5 mg / kg, and the patients underwent mechanical ventilation by mask for three minutes. Then the airway is protected by LMA and the patient is attached to the anesthetic machine and is mechanically ventilated and maintained anesthetized with iso-fluorine 0.8-1.2 Mac, with oxygen and N2O of 50%.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz Hospital

Full name of responsible person

Hamidreza Shetabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available