

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation and comparison of cardiovascular response to laryngoscopy and endotracheal intubation in induction of anesthesia with etomidate and thiopental sodium - Midazolam

Protocol summary

Study aim

Determination and comparison of cardiovascular response to laryngoscopy and endotracheal intubation in induction of anesthesia with etomidate and thiopental sodium - Midazolam

Design

A randomized double-blind clinical trial. The total sample size was 78 persons.

Settings and conduct

Following the approval of the Ethics Committee of Isfahan University of Medical Sciences, this randomized double-blind clinical trial study is performed in Isfahan 1398-1399. feiz and Alzahra hospitals, on 78 ASA-1,2 patients aged 18-70 years, from both sexes, male and female, who are candidate for Short-term surgery under general anesthesia. After obtaining informed consent from eligible patients, patients are studied in two groups of 39 persons which protecting airway with ETT.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who are candidates for short-term elective surgery (less than 2 hours) under general anesthesia; age between 18 to 70; ASA 1 & 2. Exclusion criteria: obese patients (BMI more than 25); pregnant women; uncontrolled diabetic patients; uncontrolled COPD patients; uncontrolled cardiovascular patients; chronic analgesic or sedative use; any uncontrolled systemic disease; predicting the difficulty of airway protection; any allergies to the anesthetics used

Intervention groups

After receiving 5 ml/kg of ringer lactate and pre-oxygenation for patients, induction of anesthesia was performed including Fentanyl 2 mcg/kg, Etomidate 0.3 mg/kg (in group E), Thiopental sodium 2.5 mg/kg and Midazolam 0.075 mg/kg (in group TM), and Atracurium 0.5 mg/kg (in both groups). Then 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.

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: **IRCT20180416039326N11**

Registration date: **2020-03-14, 1398/12/24**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-14, 1398/12/24**

Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Hamidreza Shetabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3620 2020

Email address

hamidshetabi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-04, 1398/12/14

Expected recruitment end date

2021-03-18, 1399/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of cardiovascular response to laryngoscopy and endotracheal intubation in induction of anesthesia with etomidate and thiopental sodium - Midazolam

Public title

Comparison of cardiovascular response to laryngoscopy and endotracheal intubation in induction of anesthesia with etomidate and thiopental sodium - Midazolam

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are candidates for short-term elective surgery (less than 2 hours) under general anesthesia Age between 18 to 70 years old ASA1&2

Exclusion criteria:

Obese patients Pregnant women Uncontrolled diabetic patients Uncontrolled COPD patients Uncontrolled cardiovascular patients Chronic analgesic or sedative use BMI more than 25 kg/m² Any Uncontrolled systemic disease Predicting the difficulty of airway protection Any sensitivity or allergies to the anesthetics agent used

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation to intervention and control groups using Random allocation software

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patient and observer who collects the information will not be in the course of the study, as the drug is injected by the planter, but the data will be collected by another person who is not in the study and the information will be double-blinded.

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

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.MUI.MED.REC.1398.622

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

Cardiovascular response

ICD-10 code

Other comp

ICD-10 code description

T88.5

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

Barometer

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

Barometer

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, induction of anesthesia was performed including Fentanyl 2mcg/kg, Etomidate 0.3mg/kg, Atracurium 0.5 m/kg. Then 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

Second intervention group: after receiving 5 ml/kg of ringer lactate and pre-oxygenation for patients, induction of anesthesia was performed including Fentanyl 2mcg/kg, Thiopental sodium 2.5 mg/kg and Midazolam 0.075 mg/kg, Atracurium 0.5 m/kg. Then 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz Hospital

Full name of responsible person

Hamidreza Shetabi

Street address

Feyz Hospital , Modares St

City

isfahan

Province

Isfahan

Postal code

7346181746

Phone

+98 31 3445 2034

Email

hamidshetabi@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Hamidreza Shetabi

Street address

Al-Zahra Therapeutic Training Center, Sofeh Boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 1818

Email

hamidshetabi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaqayeq Haghjoo javanmard

Street address

Hizar jarib BLVD, Isfahan University of Medical Sciences and Health Services - Deputy of Research and Technology of the University

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 5149

Email

sh_haghjoo@med.mui.ac.ir

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

Street address

Al-Zahra Therapeutic Training Center, Sofeh Boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

hamidshetabi@med.mui.ac.ir

Person responsible for scientific 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

Street address

Al-Zahra Therapeutic Training Center, Sofeh Boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

hamidshetabi@med.mui.ac.ir

Person responsible for updating data**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

Street address

Al-Zahra Therapeutic Training Center, Safeh Boulevard

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

hamidshetabi@med.mui.ac.ir

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