

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Propofol alone and Propofol with Muscle relaxant on hemodynamic and LMA insertion condition during induction of anesthesia

Protocol summary

Study aim

Comparison of Propofol alone and Propofol with Muscle relaxant on hemodynamic and laryngeal mask airway insertion condition during induction of anesthesia.

Design

A double-blind clinical trial, with Parallel and randomized groups of 70 patients ranging in age from 18 to 65 years with ASA I and II who is candidates for elective surgery. Randomization will be done based on Block Randomization method using Allocation Random software.

Settings and conduct

This double blind clinical trial study will be conducted at Shahid Mohammadi hospital in Bandar Abbas. LMA with appropriate size will be improvised in sniffing position and the data will be recorded by an anesthesiologist who is not aware of the study

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients between 18-65 years of age, physical condition (ASA I and II), are candidates for elective surgery. Non-inclusion criteria: drug allergy, emergency patients, patients with full stomach, patients with a history of upper respiratory tract infection, high intra cranial pressure (ICP), asthma, COPD, obesity (BMI<40)

Intervention groups

Intervention group 1: Intravenous injection of 2.5 mg/kg propofol with saline (Dose equal to cisatracurium).
Intervention group 2: Intravenous injection of 2.5 mg/kg propofol with 0.2 mg/kg cisatracurium.

Main outcome variables

Patient hemodynamic situation; laryngeal mask airway insertion (LMA)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200108046052N1**

Registration date: **2020-02-28, 1398/12/09**

Registration timing: **prospective**

Last update: **2020-02-28, 1398/12/09**

Update count: **0**

Registration date

2020-02-28, 1398/12/09

Registrant information

Name

Motahareh Khojastehrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 76 3380 0885

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-29, 1398/12/10

Expected recruitment end date

2020-03-29, 1399/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Propofol alone and Propofol with Muscle relaxant on hemodynamic and LMA insertion condition during induction of anesthesia

Public title

Use of muscle relaxants in laryngeal mask airway insertion

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patient age between 18-65 years Physical Condition (ASA I and II) Candidate for elective surgery
Exclusion criteria:
Drug sensitivity Emergency patients Patients with full stomach Patients with a history of upper respiratory tract infection Asthma COPD Obesity BMI <40 High ICP

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation was done using block randomization method and Random Allocation software and 70 patients were divided into two groups of 35 patients.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are unaware of being in which group. LMA insertion and data recording was done by an experienced anesthesiologist who was not aware of the study process.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Bandar abbas University of Medical Sciences
Street address
Republic Street, Shahid Mohammadi Hospital
City
Bandar Abbas
Province
Hormozgan

Postal code
7919915519
Approval date
2017-01-11, 1395/10/22
Ethics committee reference number
HUMS.REC.1394.104

Health conditions studied

1

Description of health condition studied
Finding an easy and safe way to operate LMA with minimal complications
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hemodynamic changes after injection
Timepoint
Before induction of anesthesia, before, during, and 1, 3 and 5 minutes after LMA insertion
Method of measurement
Hemodynamic changes registration form

2

Description
The laryngeal mask airway insertion status after injection
Timepoint
Evaluation of LMA insertion variable changes before, during, and 1, 3 and 5 minutes after LMA insertion.
Method of measurement
Ease of masking table, table parameters during insertion, removal of the LMA and duration of surgery.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intravenous propofol 2.5 mg/kg(PROPOFOL1 mg/10 ml, B Braun Co, in Germany) and 0.2 mg/kg cisatracurium (muscle relaxant)(Cisatrecurium 10mg/5ml Rosamed-Iran) were injected. After 4 minutes of ventilation with pure oxygen, the LMA of appropriate size was standardized by an anesthesiologist who was unaware of the study and the information was recorded in a form.
Category
Treatment - Drugs

2

Description

Control group: 2.5 mg/kg propofol (PROPOFOL1 mg/10 ml, B Braun Co, in Germany) and normal saline were injected with equal volume of relaxant. After 4 minutes of ventilation with pure oxygen, the LMA of appropriate size was standardized by an anesthesiologist who was unaware of the study and the information was recorded in a form.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mohammadi Hospital

Full name of responsible person

Hashem Jarineshin

Street address

Shahid Mohammadi hospital, Jomhoori street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hashem Jarineshin

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Anesthesiologist

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Master

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Only the results section can be shared.

When the data will become available and for how long

Start access period 3 months after publishing results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Announced as a reference.

From where data/document is obtainable

motahareh.khojastehrad@gmail.com

What processes are involved for a request to access data/document

Send request by email

Comments