Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of non-depolarizing muscle relaxant on the facilitation of laryngeal mask airway insertion

Protocol summary

Study aim

Evaluation of the effect of non-depolarizing muscle relaxant on the facilitation of laryngeal mask airway insertion

Design

This randomized double-blind clinical trial phase 3 study with parallel groups conducted on 40 patients undergoing elective surgery under general anesthesia. Patients were randomly divided into intervention and control groups based on generated computer numbers.

Settings and conduct

In this study, patients candidates for elective surgery in Urmia Imam Khomeini hospital under general anesthesia were included. The patient, outcome assessor, and anesthesiologist were blind to the belonging of the patients to the intervention or control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age group between 20 to 70 years; Classes I and II of the American Anesthesiology Society (ASA I and ASA II) and patients were candidates for elective surgery under general anesthesia. Exclusion criteria: obesity; a history of cervical spine disease; a history of drug and food allergies; congenital or acquired abnormalities in the face and airways and a history of seizures.

Intervention groups

Patients were randomly divided into two groups based on generated computer numbers. In both groups, firstly 1 mg intravenous midazolam and 2 µg intravenous fentanyl were administered per kg body weight, then patients in the intervention group received 3 mg /kg intravenous propofol with 0.1 mg/ kg intravenous atracurium and in the control group received 3 mg / kg intravenous propofol with 2 cc of intravenous normal saline.

Main outcome variables

Number of attempts to successfully LMA insertion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201207049639N4**
Registration date: **2021-01-08, 1399/10/19**
Registration timing: **retrospective**

Last update: **2021-01-08, 1399/10/19**
Update count: **0**

Registration date

2021-01-08, 1399/10/19

Registrant information

Name

Hadi Houshyar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

2019-05-22, 1398/03/01

Actual recruitment end date

2019-12-21, 1398/09/30

Trial completion date

2019-12-21, 1398/09/30

Scientific title

Evaluation of the effect of non-depolarizing muscle relaxant on the facilitation of laryngeal mask airway insertion

Public title
The effect of muscle relaxant on the facilitation of laryngeal mask airway insertion
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age group between 20-70 years Patients candidates for elective surgery under general anesthesia American Society of Anesthesiologists classification system I and II (ASA II and ASA II)
Exclusion criteria:
Obesity History of cervical spine disease History of drug and food allergies Congenital or acquired abnormalities in the face and airways History of seizures
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Actual sample size reached: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly divided into intervention and control groups using Random allocation computer software.By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients allocated into two groups according computer generated numbers. This software according to the total sample size, assigns numbers to patients up to the determined total sample size in order from number one. For example, it determines that the first patient is in the intervention group and the next patient can be in the intervention or control group. But finally the number of patients in the two groups will be equal. Based on the list of generated numbers by the software, patients were divided into two groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study was a double-blind clinical trial. The patient, outcome assessor, and the anesthesiologist who administered the drugs to the patients were blind about the type of drug and the study groups. The syringes containing the intervention or placebo were given a code and these codes were recorded for each patient. An anesthesiologist (other than the researcher) was aware of the codes, and the person who evaluated the outcomes did not know the codes.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat Street, Jahad Ave, Urmia, Iran.
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2019-05-15, 1398/02/25
Ethics committee reference number
IR.UMSU.REC.1398.066

Health conditions studied

1

Description of health condition studied
Facilitate of insertion laryngeal mask airways (LMA)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The number of attempts for successfully LMA insertion
Timepoint
During the insertion of laryngeal mask
Method of measurement
The number of attempts

Secondary outcomes

1

Description
Sore throat
Timepoint

After the laryngeal mask insertion

Method of measurement

Clinical examination

2

Description

Laryngospasm

Timepoint

After the laryngeal mask insertion

Method of measurement

Clinical examination

Intervention groups

1

Description

Intervention group: Patients in the intervention group after receiving of intravenous midazolam 1 mg and Intravenous fentanyl 2 mg, they received 3 mg / kg of intravenous propofol with 0.1 mg / kg of intravenous atracurium.

Category

Treatment - Surgery

2

Description

Control group: Patients in the control group after receiving of intravenous midazolam 1 mg and Intravenous fentanyl 2 mg, they received 3 mg / kg of intravenous propofol with 2 cc of intravenous normal saline.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Imam Khomeini hospital

Full name of responsible person

Dr. Hadi Hooshyar

Street address

Imam Khomeini hospital, Ershad street, Modarres Blvd., Urmia, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Hadi Hooshyar

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Position
Assistant professor

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Person responsible for updating data

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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
Not applicable

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
The results of the study will be published as an article.

When the data will become available and for how long
After publishing the article

To whom data/document is available
Researchers

Under which criteria data/document could be used
As published article

From where data/document is obtainable
Corresponding author

What processes are involved for a request to access data/document
By email address of corresponding author

Comments