Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of laryngeal mask insertion (LMA) with classical methods, triple maneuver and rotation on cardiovascular response

Protocol summary

Study aim
Determining the effect of the laryngeal mask (LMA) insertion with three classical methods, triple maneuver and rotation on cardiovascular response

Design
Clinical trial without control group, with parallel groups, double-blind, randomized, phase 3 on 90 patients, randomization with Random Allocation software

Settings and conduct
People who meet the criteria for entering the study will be included in the study in the elective operating room by easy sampling. Then, using the resulting list method from the randomization software, they will be placed in one of the studied groups, including LMA embedding in the classic method, LMA embedding in the rotation method, and LMA embedding in the triple maneuver method.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1) Age over 18 years 2) Physical status I or II according to the American Society of Anaesthesiologists 3) Informed consent to participate in the study 4) Candidate patients for airway management with a laryngeal mask Criteria for not entering the study: 1) People with a difficult airway with oral inlet less than 2.5 cm or difficult intubation (mallampati>3, TMD<6.5) 2) People with a high risk of aspiration, including non-fasting people, people with GERD, and pregnant people 3) History of the common cold in the last 10 days 4) History of head and neck or stomach surgery 5) Coagulopathy 6) BMI>30 7) Uncontrolled cardiovascular, pulmonary and liver disease

Intervention groups
Individuals will be placed in one of the studied groups, including LMA embedding in the classic method, LMA embedding in the rotational method, and LMA embedding in the triple maneuver method.

Main outcome variables
Changes in blood pressure, heart rate and percentage of arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039326N22**
Registration date: **2023-06-11, 1402/03/21**
Registration timing: **retrospective**

Last update: **2023-06-11, 1402/03/21**
Update count: **0**

Registration date
2023-06-11, 1402/03/21

Registrant information

Name
Hamidreza Shetabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-20, 1401/12/01

Expected recruitment end date
2023-05-21, 1402/02/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of laryngeal mask insertion (LMA) with classical methods, triple maneuver and rotation on cardiovascular response

Public title
The effect of three different methods of laryngeal mask insertion (LMA) on cardiovascular response
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Older than 18 years old I or II physical condition based on American Society of Anaesthesiologists Informed consent of participate in research Candidate patients for airway management using a laryngeal mask airway
Exclusion criteria:
People with difficult airway with mouth inlet less than 2.5 cm or difficult intubation (mallampati>۳ ، TMD< ۶.۵) People at high risk of aspiration include non-fasting, GERD sufferers, and pregnant people Patient with a history of sore throat in the last month History of the common cold in the last 10 days History of head and neck or stomach surgery Coagulopathies BMI>30 Uncontrolled cardiovascular, pulmonary and liver disease
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the table of random numbers obtained from the Random Allocation software, patients are randomly assigned to one of the LMA insertion groups using the classic method, the triple maneuver method, and the rotation method, and are included in the study. https://mahmoodsaghaei.tripod.com/Softwares/randalloc.html
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the patient and the person collecting the data will be unaware of the laryngeal mask airway placement method.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Committee of Isfahan University of Medical Sciences
Street address
No. 4, 3rd Sajjadiyeh Alley, Artesh Blvd, Farahabad
City
Isfahan
Province
Isfehan
Postal code
1111111111
Approval date
2023-01-02, 1401/10/12
Ethics committee reference number
IR.MUI.MED.REC.1401.353

Health conditions studied

1

Description of health condition studied
effect of oropharyngeal stimulation on cardiovascular response during laryngeal mask airway implantation
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mean atrial pressure
Timepoint
Basic time and in 1, 3, and 5 minutes after installing the laryngeal mask
Method of measurement
Blood pressure monitor

2

Description
Heart rate
Timepoint
Basic time and in 1, 3, and 5 minutes after installing the laryngeal mask
Method of measurement
Heart monitor

3

Description
Arterial O2 saturation
Timepoint
Basic time and in 1, 3, and 5 minutes after installing the laryngeal mask
Method of measurement
Pulse oximeter device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: According to the weight of patients, LMA size 3 (weight less than 50 kg) or size 4 (weight 70-50 kg) or size 5 (weight 71 kg or more) is selected and according to the principles of classic method, the mask will be placed in the sniffing position. The person placing the LMA masks has at least two years of experience in this field.
Category
Treatment - Devices

2

Description
Intervention group: According to the weight of patients, LMA size 3 (weight less than 50 kg) or size 4 (weight 70-50 kg) or size 5 (weight 71 kg or more) is selected and according to the principles of triple maneuver method, the mask will be placed in the sniffing position. The person placing the LMA masks has at least two years of experience in this field.
Category
Treatment - Devices

3

Description
Intervention group: According to the weight of patients, LMA size 3 (weight less than 50 kg) or size 4 (weight 70-50 kg) or size 5 (weight 71 kg or more) is selected and according to the principles of rotational method, the mask will be placed in the sniffing position. The person placing the LMA masks has at least two years of experience in this field.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Zahra Naserzadeh
Street address
Alzahra hospital, soffeh Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
shaghayegh haghjooye javanmard
Street address
No 4, Medical university of Isfahan, Hezarjarib Ave.
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8174673461
Phone
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Email
research@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
Associate Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data is potentially shareable after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions
Under which criteria data/document could be used
There are no special conditions
From where data/document is obtainable
hamidshetabi@med.mui.ac.ir
What processes are involved for a request to access data/document
The request will sent to the researcher and the information is provided after checking
Comments