Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Comparison of four insertion techniques of laryngeal mask airway: standard, 90-degree rotation, 180-degree rotation and insertion with thumb finger

Protocol summary

Study aim

Achieving the most effective and least complicated method among four insertion techniques of laryngeal mask airway: standard, 90-degree rotation, 180-degree rotation, and insertion with thumb finger.

Design

Study of a double-blind randomized clinical trial (statistician and patient) on patients undergoing elective surgery requiring anesthesia divided into four groups of at least 63 patients, a total of 252 patients, and randomization with random allocation software

Settings and conduct

A double-blind, randomized, double-blind clinical trial will be performed on 252 patients aged 18 to 80 years with II and ASA I who are candidates for elective surgery. Random allocation will be done using Block Randomization method and Allocation Random software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18-80 years; Physical status of the American Society of Anesthesiologists Level I and II. Exclusion Criteria: People with difficult airway with mouth opening less than 2.5 cm; People at high risk for aspiration, including non-fasting people with gastroesophageal reflux disease and pregnancy; Patients with a history of sore throat in last month; Colds during the last 10 days; History of head, neck, and stomach surgery; Difficult intubation (mallampati> 3, TMD> 6.5); Coagulopathy 8. BMI> 30

Intervention groups

1. Standard method group 2. 90 degree rotation 3. Rotate 180 degrees 4. Placement with the thumb

Main outcome variables

Evaluation of hemodynamic changes, the success rate in mask placement and complications (laryngospasm, presence of blood on the mask, and sore throat)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190127042511N2**
Registration date: **2021-11-29, 1400/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2021-11-29, 1400/09/08**
Update count: **0**

Registration date

2021-11-29, 1400/09/08

Registrant information

Name

Alireza Babaeizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3669 4561

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of four insertion techniques of laryngeal mask airway: standard, 90-degree rotation, 180-degree rotation and insertion with thumb finger

Public title
Comparison of four insertion techniques of laryngeal mask airway: standard, 90-degree rotation, 180-degree rotation and insertion with thumb finger

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ASA 1 or 2 Age 18 to 80 years

Exclusion criteria:
People with difficult airway with mouth openin less than 2.5 cm People at high risk for aspiration include non-fasting people with gastroesophageal reflux disease and pregnancy Patients with a history of sore throat in a recent month History of head, neck and stomach surgery Colds in the last 10 days Difficult intubation (mallampati> 3, TMD> 6.5) Coagulopathy BMI>30

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **252**

Randomization (investigator's opinion)
Randomized

Randomization description
For the block randomization method, the letter A is used to place patients in the "standard" group, the letter B is used for the "90 degree rotation" group, the letter C is used for the "180 degree rotation" group, and the number D is used for the "thumb placement" group. The size of all blocks is equal and in this four-group experiment, we use 4 blocks (including one person in group A, one person in group B and one person in group C, and one person in group D) that use soft Random sequence generation software will be obtained. Also, in order to hide the random sequence on the participants, opaque sealed envelopes sealed with random sequences are used and each sequence is recorded on a card, and the cards are placed in the envelopes respectively. Based on the order of entry of eligible participants in the research, the envelopes are opened in order and the assigned group of the participant is determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are not aware of being in groups. LMA insertion and data entry is performed by an experienced anesthesiologist. The information analyzer does not know about individuals (coding)

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
Hezar Jerib Ave

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-11-02, 1400/08/11

Ethics committee reference number
IR.MUI.MED.REC.1400.611

Health conditions studied

1

Description of health condition studied
Insertion of LMA

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
First try attempt success rate of LMA insertion

Timepoint
After LMA insertion

Method of measurement
Observation

2

Description
Mean arterial pressure

Timepoint
1min before LMA insertion and 1 , 5 min after interion

Method of measurement
NIBP

3

Description

End tidal CO2

Timepoint

After insertion

Method of measurement

Capnography

4

Description

Spo2

Timepoint

Base time (at rest),1min before LMA insertion and 1,5 min after insertion

Method of measurement

Puls oximeter

5

Description

Heart rate

Timepoint

Base time (at rest),1min before LMA insertion and 1,5 min after insertion

Method of measurement

Monitoring

6

Description

Side effects of masking include laryngospasm; blood on the mask; sore throat

Timepoint

When LMA removed

Method of measurement

Observation

7

Description

Calf air pressure need to prevent leakage

Timepoint

After insertion of LMA

Method of measurement

barometer

8

Description

Need for repositioning

Timepoint

At time of insertion

Method of measurement

Observation

9

Description

Attempts for insertion (1,2 or 3 times)

Timepoint

At time of insertion

Method of measurement

Observation

10

Description

Total successful rate of LMA intertion

Timepoint

At time of insertion

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Standard method of LMA insertion ; In this method, the LMA mask is inserted using the index finger and advanced to the palatopharyngeal flexion to reach the hypopharynx to finally reach a real resistance.

Category

Treatment - Devices

2

Description

Intervention group: 90 degree rotation method of LMA insertion ؛ In this method, the LMA mask is inserted into the mouth in such a way that its inner layer is towards the buccal mucus and the corner of the mouth. Here the mask is pushed forward to finally hit the resistance.

Category

Treatment - Devices

3

Description

Intervention group: 180 degree rotation method of LMA insertion ؛ In this method, the LMA mask is inserted into the mouth while the inner layer is placed towards the hard palate (contrary to the standard method) and is pushed forward until it encounters resistance. The LMA mask is then rotated 180 degrees and the cuff is inflated.

Category

Treatment - Devices

4

Description

Intervention group: LMA insertion with thumb finger ؛In this method, the anesthesiologist first places the patient on the patient's face in front of the patient's chest and right arm. After partially inflating the cuff (equivalent to half the air recommended for inflating the mask), the posterior surface of the cuff will be lubricated with a blue water-based gel.The patient's head is supported by a tight ring while the patient's neck is flex and the patient's head is extended. The tubular part of the laryngeal mask is held in an automatic manner, and unlike the standard method, the part connected to the tube is taken with the thumb. After opening the patient's

mouth, the head of the mask is placed opposite the inner surface of the upper canines, while its opening is towards the front. The mask is then pressed against the hard palate to reach the hypopharyngeal area and resist. In this method, the thumb will be used to apply pressure against the hard palate and push the LMA mask forward

Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
Seyed Jala Hashemi
Street address
Kashani Ave
City
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2

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
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8174673461
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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
Seyed Jalal Hashemi
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
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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 unidentified individuals

When the data will become available and for how long
Six months after the results were published

To whom data/document is available
Academic researchers

Under which criteria data/document could be used
Scientific uses

From where data/document is obtainable
Isfahan University of Medical Sciences website

What processes are involved for a request to access data/document
Clear request on the site for access to data by the individual and then review the request by the research assistant within 2 weeks and then permission to access the data.

Comments