

# 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

alirezabbz@yahoo.com

##### 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 opening 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 analyst

**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

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Isfahan

**Province**

Isfahan

**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 insertion

**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**

Isfahan

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### 2

#### Recruitment center

**Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Seyed Jalal Hashemi

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## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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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 scientific inquiries

#### Contact

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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

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
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Professor  
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