

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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)

##### Phone

+98 31 3620 2020

##### Email address

hamidshetabi@med.mui.ac.ir

##### 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

Isfahan

##### 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

+98 31 3620 2020

### Email

drzahra9776@gmail.com

## 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

##### City

Isfshsn

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

## 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.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8138

##### 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

##### Street address

Soffeh BLVD. Alzahra hospital

##### City

Isfahan

##### Province

Isfahan  
**Postal code**  
8174675731  
**Phone**  
+98 31 8222532  
**Fax**  
**Email**  
hamidshetabi@med.mui.ac.ir

## Person responsible for scientific 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  
**Street address**  
Modarres st.feiz hospital  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
7346181746  
**Phone**  
+98 31 3620 2020  
**Fax**  
**Email**  
Hamidshetabi@med.mui.ac.ir

## Person responsible for updating data

### 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  
**Street address**  
Modarres st.feiz hospital  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
7346181746  
**Phone**  
+98 31 3620 2020  
**Fax**  
**Email**  
hamidshetabi@med.mui.ac.ir

## 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