

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The comparison of hemodynamic effects of the classic laryngeal mask airway, laryngeal mask airway supreme and laryngoscopy for endotracheal tube insertion in patients undergoing elective surgery.

#### Protocol summary

##### Summary

Our aim is to compare the hemodynamic responses using three different airway devices; laryngeal mask airway Supreme (LMA-S), classic laryngeal mask airway (LMA-C) and laryngoscopy with endotracheal intubation (ETT). This is a prospective randomized, double blind clinical trial. Inclusion: 18-50 years old, ASA I, elective minor to moderate scale surgical operations. Exclusion: Facial deformities and cases of difficult airway management. The sample of 150 patients will be randomly assigned to one of these three device groups which are selected from the population of patients who are admitted to Shahid Mohammadi Hospital, Bandar Abbas, Iran. The study will be done in one month period. Laryngoscopy will be done with a McIntosh number 3 blade for ETT, and the other two groups' one with LMA Classic and other group with LMA Supreme. Anesthesia induction and maintenance will be similar in all three groups. After the airway intervention and confirming the patency of airway through the devices and the establishment of the control breathing: Blood pressure systolic and diastolic and the heart rate will be measured before induction of anesthesia and at 4 other sequential stages afterwards. Primary outcomes: better profile with LMAs.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014061518091N1**  
Registration date: **2015-05-20, 1394/02/30**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-20, 1394/02/30

##### Registrant information

###### Name

Fekrat Fereydoon

###### Name of organization / entity

Hormozgan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 76 3334 4009

###### Email address

fereydoon.fekrat@hums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

governmental resources of Shahid Mohammadi Hospital, Hormozgan University of Medical Sciences

##### Expected recruitment start date

2014-07-23, 1393/05/01

##### Expected recruitment end date

2014-08-23, 1393/06/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The comparison of hemodynamic effects of the classic laryngeal mask airway, laryngeal mask airway supreme and laryngoscopy for endotracheal tube insertion in patients undergoing elective surgery.

##### Public title

Comparing the effects of different airway devices on the patients blood pressure and heart rates.

## Purpose

Other

## Inclusion/Exclusion criteria

Inclusion criteria: male or female; 18-50 years old; ASA I status; elective minor to moderate scale surgical operations. Primary exclusion criteria: emergency operations; major scale operations (neurosurgery, major thoracic and abdominal surgery); full stomach patients; BMI>35 kg/m<sup>2</sup>; patients with history of cardiovascular disease; metabolic and endocrinal pathologies that needed special care perioperatively. Patients with head and neck malformations that may cause difficult airway management.

## Age

From **18 years** old to **50 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **150**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Not used

## Assignment

Single

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Deputy for Research, and Medical Ethics Committee of Hormozgan University of Medical Sciences

##### Street address

Joomhoori Islami Blv., Shahid Mohammadi Hospital, Bandar Abbas, Iran.

##### City

Bandar Abbas

##### Postal code

#### Approval date

2014-01-22, 1392/11/02

#### Ethics committee reference number

HEC-92-11-2-2

## Health conditions studied

### 1

#### Description of health condition studied

Laryngeal mask

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

changes in systolic and diastolic blood pressures and heart rates

#### Timepoint

before starting induction of anesthesia - after induction- before intervention of the airway devices- immediately after device intervention- at times 1 ,3,5 minutes after device interventions

#### Method of measurement

measurements by monitor that has automatic NIBP and HR from the ECG monitor

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Pre induction hydration was done with 7 mL/kg Ringer solution in all patients. Premedication was provided by intravenous midazolam (0.05 mg/kg) and fentanyl (2mcg/kg). Anesthesia was induced with propofol (2mg/kg) and atracurium (0.5 mg/kg) after a sufficient relaxation based on (TOF = 0) the patients airway patency was maintained by a Classic Laryngeal Mask Airway

#### Category

Other

### 2

#### Description

Pre induction hydration was done with 7 mL/kg Ringer solution in all patients. Premedication was provided by intravenous midazolam (0.05 mg/kg) and fentanyl (2mcg/kg). Anesthesia was induced with propofol (2mg/kg) and atracurium (0.5 mg/kg) after a sufficient relaxation based on (TOF = 0) the patients airway patency was maintained by a Supreme Laryngeal Mask Airway.

#### Category

Other

### 3

#### Description

Pre induction hydration was done with 7 mL/kg Ringer solution in all patients. Premedication was provided by intravenous midazolam (0.05 mg/kg) and fentanyl

(2mcg/kg). Anesthesia was induced with propofol (2mg/kg) and atracurium (0.5 mg/kg) after a sufficient relaxation based on (TOF = 0) the patients airway patency was maintained by laryngoscopy and tracheal intubation.

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shahid Mohamadi Hospital

**Full name of responsible person**

Fereydoon Fekrat

**Street address****City**

Bandar Abbas

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Hormozgan University of Medical Sciences

**Full name of responsible person**

Abdulazim Nejatizadeh

**Street address**

Joomhoori Islami Blv. Deputy of Research Center, Shahid Mohammadi Hospital, Bandar Abbas, Iran.

**City**

Bandar Abbas

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hormozgan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

HUMS

**Full name of responsible person**

Fereydoon Fekrat

**Position**

specialist in Anesthesiology and Intensive care

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*