Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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/m2; 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- immidiately after device intervention- at times 1 ,3,5 minutes after device interventions
Method of measurement
measurments by monitor that has auotomatic 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

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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

Other areas of specialty/work

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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