Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the efficacy of laryngeal mask Airway (LMA) compared to endotracheal tube (ETT) in thoracic and abdominal surgeries general anesthesia.

Protocol summary

Study aim

Evaluation of the efficacy of laryngeal mask Airway (LMA) compared to endotracheal tube (ETT) in thoracic and abdominal surgeries for more than 2 hours under general anesthesia in Fatemeh hospital.

Design

This study is a randomized, double-blind clinical trial with a sample size of 100, which is randomly assigned to two groups. On the airway the first group is wearing a laryngeal mask. In the second group, the endotracheal tube is inserted.

Settings and conduct

In this study, 100 patients undergoing thoracic and abdominal surgery will be divided into two groups including laryngeal mask and endotracheal tube and all patients will receive the same premedication and induction. In the first group of LMA the appropriate size is 3, 4 or 5 according to the recommendation of the manufacturer with standard placement. In the second group, ETTs are 7 or 7.5 for female patients and 7.5 or 8 for male patients. All patients receive propofol during surgery. Both groups were studied for variables such as age, sex, Malampathy Class and BMI. The study was performed in Fatemeh Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Physical Status Classification System 1 or 2 Patient satisfaction to participate in the study Age range between 25 and 60 years, Exclusion criteria: Patient dissatisfaction to participate in the study, Patients not fasting, Latex sensitivity History of colds in the last 10 days

Intervention groups

Intervention group one: Applying laryngeal mask (LMA) to airway management of patients undergoing general anesthesia for thoracic and abdominal plastic surgery Intervention group II: Use of endotracheal tube (ETT) for airway management of patients undergoing general anesthesia for thoracic and abdominal plastic surgery

Main outcome variables

Damage to the airway, Easier placement, Bronchospasm

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110513006465N2**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date

2020-03-14, 1398/12/24

Registrant information

Name

Seyed Alireza Seyed Siamdoust

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 1749

Email address

siamdoust.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-21, 1398/01/01

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the efficacy of laryngeal mask Airway (LMA) compared to endotracheal tube (ETT) in thoracic and abdominal surgeries general anesthesia.

Public title
Evaluation of the efficacy of laryngeal mask Airway (LMA) compared to endotracheal tube (ETT) in thoracic and abdominal surgeries for under general anesthesia.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ASA Physical Status Classification System 1 or 2 Patient satisfaction to participate in the study Age range between 25 and 60 years
Exclusion criteria:
Patient dissatisfaction to participate in the study Patients not fasting Latex sensitivity History of colds in the last 10 days
Age
From **25 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a double-blind randomized clinical trial in which the number of patients is determined according to the sample size formula and using a simple randomization method, which uses a random number table for each patient. The code is given and patients are randomly assigned to two treatment groups, with random code selection.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, patients are not aware of the placement in the study groups, and the person who analyzes the information collected does not know the study groups and is given information in groups A and B.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Iran University of Medical Sciences., Hemmat Highway., Next to Milad Tower., Tehran Town
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2020-03-01, 1398/12/11
Ethics committee reference number
IR.IUMS.FMD.REC.1398.539

Health conditions studied

1

Description of health condition studied
Thoracic Surgery
ICD-10 code
G54.3
ICD-10 code description
Thoracic root disorders, not elsewhere classified

Primary outcomes

1

Description
Effects on airway after intubation in anesthesia
Timepoint
During surgery and after surgery
Method of measurement
checkup

Secondary outcomes

1

Description
Sore Throat
Timepoint
After surgery
Method of measurement
Examination

Intervention groups

1

Description
Intervention group 1: LMA masks of suitable size 3, 4 or 5 as recommended by the manufacturer (manufactured by IranFormis) before surgery and once. LMA cuff slowly fills until sound Don't hear from Leak Cuff. The LMA cuff pressure is filled in by a pressure gauge of 30 to 40 cm.
Category
Treatment - Devices

2

Description
Intervention group 2: Placement of an endotracheal tube size 7 or 7/5 for female patients and size7/5 or 8 for male patients according to the recommendation of the manufacturer (production of teb tolid company) before surgery and once. The cuff is filled up to 25 mm Hg.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrate Fatemeh Hospital
Full name of responsible person
Seyed Alireza Seyed Siamdoust
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21th Str., Asadabadi Ave., Hazrate Fatemeh Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Vice Chancellor for Research & Technology
Street address
21th Str., Asadabadi Ave., Hazrate Fatemeh Hospital
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Seyed Alireza Seyed Siamdoust
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available