

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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, Mallampaty 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

AgeFrom **25 years** old to **60 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget 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

۱۳۴۹۶۱۴۵۳۵

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 size 7/5 or 8 for male patients according to the recommendation of the manufacturer (production of teb toolid 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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Email

alireziasiamdoust@gmail.com

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 scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

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Position

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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

Person responsible for updating data**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