

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation of success rate of classic Laryngeal mask insertion on the first try with three different technique: the classic methods, lateral and rotational in obese patients with BMI more than 30

Protocol summary

Summary

1- Objectives: The aim of this study was to find the best way laryngeal mask insertion, in people with a body mass index over 30, which could lead to less complications in patients. 2- Design: In this study insertion of laryngeal mask in patients undergoing general anesthesia are, to classical methods, will be compared with lateral and rotational. The best method with the least side effects is indicated in patients with a body mass index above 30 is used. 3- Setting and conduct: After ethical approval by the Tabriz University of Medical Sciences faculty of medicine , 135 patients with the BMI more than 30 candidates for orthopedic surgeries with anesthesia will be studied in this prospective clinical trial, and randomly divided into three groups using the software will be made. Induction of the anesthesia will be similar in all patients including : pre-oxygenation by 100% oxygen , Midazolam 0.03 mg/kg , Fentanyl 1-2 µg/kg , Propofol 2-3 mg/kg .An anesthesiologist which is expert in inserting LMA in 20-30 seconds will insert the LMA with three techniques standards , lateral and rotational . the patients will be monitored by NIBP, HR, ECG, Pulse Oximetry and ETCO₂. 4- Participants outcome including major eligibility criteria; Inclusion criteria: The obese patients with BMI more than 30 ; Candidate for anesthesia with laryngeal mask insertion. Exclusion criteria: Body mass index less than 30; During the operation more than 2 hours; Other than the supine position surgery; In head and neck surgery; Patients at risk for aspiration; Patients known to have airway problems; Multiple attempts to put the laryngeal mask. 5- Intervention: laryngeal mask to classical methods, Insertion of laryngeal mask to classical methods, lateral and rotational in patients with a body mass index over 30 by the anesthesiologist. 6- Main (measures) variables: The data to be recorded will be: LMA insertion time, number of insertion tries, leak

around LMA and grading it by ventilation with the pressure of 20 cmH₂O as: Grade one: no leak; Grade two: feeling of leak; Grade three: feeling of leak with sound with appropriate ventilation; Grade four: feeling of leak with sound with inappropriate ventilation; Grade five: complete airway obstruction. Assessment of appropriate ventilation using: ETCO₂ , good chest movements and continuous oxygenation. complications like blood on the mask of LMA , sore throat as none , mild , moderate and severe and any change in patient voice will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510107313N4**

Registration date: **2015-12-02, 1394/09/11**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-12-02, 1394/09/11

Registrant information

Name

Mirmohammadtaghi Mortazavi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

The costs of patient surgery and additional costs for projects not required. Through Medical insurance will be provided.

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of success rate of classic Laryngeal mask insertion on the first try with three different technique: the classic methods, lateral and rotational in obese patients with BMI more than 30

Public title

Evaluation of success rate of classic Laryngeal mask insertion

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria: the obese patients with BMI more than 30 ; Candidate for anesthesia with laryngeal mask insertion Exclusion criteria: Body mass index less than 30; During the operation more than 2 hours; Other than the supine position surgery; In head and neck surgery; Patients at risk for aspiration; Patients known to have airway problems; Multiple attempts to put the laryngeal mask.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Ethics Committee of Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, I.R.Iran

City

Tabriz

Postal code

51665118

Approval date

2015-05-28, 1394/03/07

Ethics committee reference number

5/4/2398

Health conditions studied**1****Description of health condition studied**

Obesity

ICD-10 code

E66.8,

ICD-10 code description

Other obesity,

Primary outcomes**1****Description**

Success rate of the placement of the Laryngeal Mask

Timepoint

Immediately after the action

Method of measurement

The time required for proper placement of the Laryngeal Mask, The number of attempts for the Placement, Existence leakage around the laryngeal mask

Secondary outcomes

empty

Intervention groups**1****Description**

insert the LMA with standard technique

Category

Other

2**Description**

insert the LMA with rotational technique

Category

Other

3

Description

Insert the LMA with lateral technique

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Hospital

Full name of responsible person

Mirmohammadtaghi Mortazavi

Street address

Shohada Hospital, Ghoshahr Avenue, Elgoli, Tabriz, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for Research, Tabriz University of Medical Sciences

Full name of responsible person

Mortazavi Dr

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Vice-Chancellor for Research, Tabriz University of Medical Sciences, Daneshgah Avenue, Tabriz, Iran

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Tabriz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-Chancellor for Research, Tabriz 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

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Full name of responsible person

Mirmohammadtaghi Mortazavi

Position

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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