Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of efficacy, ease and speed of insertion and post operative complications of classic laryngeal mask airway (C-LMA) using four different methods in elective surgeries under general anesthesia

Protocol summary

Summary

Objectives: Comparison of efficacy, ease and speed of insertion and post operative complication of classic laryngeal mask airway (C-LMA) in four different methods in elective surgeries under general anesthesia. Design: Single blind randomized clinical trial Setting and conduct: All the participants will undergo 4 different methods of laryngeal mask insertion and the efficacy as well as complications would be compared between groups. Participants including major eligibility criteria: 200 patients scheduled for cataract surgery. Inclusion criteria: BMI 20-30; ASA I,II. Exclusion criteria: Sore throat, COPD, the patient with high risk for stomach content aspiration Intervention: Laryngeal mask insertion through 4 different methods. Main outcome measures: Efficacy, complication

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202159025N1**
Registration date: **2012-04-12, 1391/01/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-12, 1391/01/24

Registrant information

Name

Masood Zangi

Name of organization / entity

Shiraz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2012-02-29, 1390/12/10

Expected recruitment end date

2012-05-02, 1391/02/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy, ease and speed of insertion and post operative complications of classic laryngeal mask airway (C-LMA) using four different methods in elective surgeries under general anesthesia

Public title

Comparison of four ways for insertion of laryngeal mask

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Body Mass Index (BMI) ranging from 20 to 30; ASA I,II Exclusion Criteria: Upper respiratory tract infection; sore throat; COPD; patients with high risk of aspiration (e.g Diabetes, gasteroesophagial reflux, diaphragmatic hernia, operation for more than 2 hours, position except supine and lithotomy)

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Shiraz University of Medical Sciences

Street address

Ethics Committee, 7th Floor, Shiraz University of Medical Sciences central building, Zand Avenue

City

Shiraz

Postal code

71345-1978

Approval date

2012-02-12, 1390/11/23

Ethics committee reference number

CT-90-1898

Health conditions studied

1

Description of health condition studied

Cataract

ICD-10 code

H25.0

ICD-10 code description

Senile incipient cataract

Primary outcomes

1

Description

Laryngeal mask insertion time

Timepoint

During mask insertion, 1 and 6 hours later

Method of measurement

Chronometer

2

Description

Successful laryngeal mask insertion

Timepoint

During mask insertion

Method of measurement

Incidence (Percentage)

3

Description

Complication of laryngeal mask insertion

Timepoint

During mask insertion, 1 and 6 hours later

Method of measurement

Incidence (Percentage)

Secondary outcomes

1

Description

Incidence of hoarseness

Timepoint

1 and 6 hours after operation

Method of measurement

Incidence (Percentage)

2

Description

Incidence of sore throat

Timepoint

1 and 6 hours after operation

Method of measurement

Incidence (Percentage)

3

Description

Incidence of neck pain

Timepoint

1 and 6 hours after operation

Method of measurement

Incidence (Percentage)

Intervention groups

1

Description

1st Method: Standard method: The patient’s head is extended by one hand and the proximal part of LMA is placed in the other hand in such a way that it is entered the patient mouth from gap surface side. Then, the LMA

is moved along the hard palate with the forefinger until a resistance is felt due to oropharynx and the cuff is expanded based on manometer and finally the leakage is checked.

Category

Treatment - Surgery

2

Description

2nd Method: Lateral method: The patient's head is extended by one hand and the proximal part of LMA is placed in the other hand in such a way that it is entered the patient mouth as standard method in such a way that the entire cuff is located in mouth. Then, the cuff is rotated at 45 degree angle laterally in such a way that only tongue side is in contact with mask edge. Then, the forefinger and thumb is used to move it along the mouth until a resistance is felt. Finally, the mask is rotated 45 degree in opposite direction and located in middle position and the cuff is expanded based on manometer and leakage is checked.

Category

Treatment - Surgery

3

Description

3rd Method: Rotational method: The patient's head is extended by one hand and the proximal part of LMA is placed in the other hand in such a way that it is entered the patient mouth with 180 degree angle (the mask gap is toward hard palate). Then, it is moved along the mouth until a resistance is felt. Finally, it is rotated 180 degree and fixed behind the larynx and the cuff is expanded based on manometer and leakage is checked, and the cuff is expanded based on manometer and leakage is checked.

Category

Treatment - Surgery

4

Description

4th Method: Modified standard method: This method is similar to the standard method except for the mask is moved in its paths without using any fingers.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam

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Vice chancellor for research, 7th floor, Shiraz University of Medical Sciences central building, Zand Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Shiraz

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, Shiraz 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

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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