

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two methods of LMA insertion, Classic method and using a Laryngoscope.

Protocol summary

Study aim

Comparison of two methods of LMA insertion, Classic method and using a Laryngoscope.

Design

Clinical trial with parallel groups, including two groups by stratified random method and a total of four strata, in each stratum random permutation block method is used. Randomization tool: table of random numbers. Blinding: not used. Sample size: 106 people.

Settings and conduct

Patients are included in the study based on the inclusion criteria and are divided into two groups of 53 people with stratified random technique. Classes are made based on age group and gender (four classes in total). Within each class, the method of random permutations is used to assign patients to two groups. The randomization tool will be a table of random numbers. In the first group, LMA is implanted in the classical way, in the second group, LMA is implanted using a laryngoscope. In the research, it is done in Ashair hospital of Khorramabad. blinding was not used.

Participants/Inclusion and exclusion criteria

Conditions for entering the study: 1. Elective surgery patients in Khorramabad Ashayer Hospital, in 2023 2. Patients with ASA class 1 and 2. 3. Patients with minor surgery. 4. Patients aged 18 to 65 years 5. Informed patients with written consent Conditions of not entering the study: 1. Patients with head and face injuries and head and neck abnormalities 2. Patients who have contraindications for LMA placement: such as high risk of aspiration, not fasting, pregnancy 3. Patients with difficult Airway

Intervention groups

1. Classic method, 2. using a laryngoscope.

Main outcome variables

comparison of the complications of LMA placement: presence of blood on the LMA, presence of air in the stomach, tooth damage, severity of sore throat (VAS criterion); comparison of LMA insertion time; The number

of attempts to successfully insert LMA; level of doctor's satisfaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230716058802N1**

Registration date: **2023-07-29, 1402/05/07**

Registration timing: **prospective**

Last update: **2023-07-29, 1402/05/07**

Update count: **0**

Registration date

2023-07-29, 1402/05/07

Registrant information

Name

Aram Azizi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3321 5410

Email address

aram.azizi0212@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-05, 1402/05/14

Expected recruitment end date

2023-09-05, 1402/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of LMA insertion, Classic method and using a Laryngoscope.

Public title

Comparison of two methods of Laryngeal Mask Airway insertion, Classic method and using a Laryngoscope.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Elective surgery patients in Khorramabad Ashayer Hospital ,in 1402, Patients with ASA class 1 and 2. Patients with minor surgery. Patients aged 18 to 65 years Informed patients with written consent

Exclusion criteria:

Patients with head and face injuries and head and neck abnormalities Patients who have contraindications for LMA placement: such as high risk of aspiration, not fasting, pregnancy Patients with difficult Airway

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on consecutive non-probability sampling, based on the order of hospitalization, eligible patients are sampled. In this way, the classes are made based on the age groups and gender of the patient (four classes in total). Within each class, random permutation block method is used to assign to two groups. The random tool will also be a table of random numbers. Due to the nature of the anesthesia technique, it was not used in this research. The initial sample size was 44 people in each group using the variable of pain severity and based on the statistical formula, and finally, taking into account the probability of 20% dropout, the final sample size was 53 people in each group (106 in total).

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**

Ethic committee of Lorestan University of Medical Sciences

Street address

Dorud Khorramabad highway, Kmalvand, Lorestan University of Medical Sciences

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2023-07-11, 1402/04/20

Ethics committee reference number

IR.LUMS.REC.1402.127

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

Comparison of two methods of LMA insertion, Classic method and using a Laryngoscope.

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Number of attempts to successfully insert LMA

Timepoint

After LMA placement

Method of measurement

Observe

2**Description**

Duration of placement of LMA

Timepoint

After LMA placement

Method of measurement

Observe

3**Description**

Presence of blood on the LMA

Timepoint

After removing the LMA

Method of measurement

Observe

4

Description

Presence of air in the stomach

Timepoint

After removing the LMA

Method of measurement

Abdominal examination

5

Description

Severity of sore throat after surgery based on the VAS criterion

Timepoint

After the surgery is completed and the patient becomes conscious

Method of measurement

interview

6

Description

Tooth damage

Timepoint

After LMA placement

Method of measurement

Observe

7

Description

Doctor's satisfaction rate

Timepoint

After LMA placement

Method of measurement

Interview

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Placing the LMA mask in the classic way: In this method, the LMA mask is inserted into the patient's mouth by the doctor's index finger, and then it is sent to the patient's throat in the hypopharynx area in the form of a midline while in direct contact with the patient's mouth and tongue. so that the tip of the mask is in contact with the esophagus, until it finally reaches a real resistance.

Category

Treatment - Devices

2

Description

Intervention group: placement of LMA using laryngoscope: in this method, first we extend the

patient's head back, after opening the patient's mouth, we insert the laryngoscope from the right side of the patient's mouth and open the oral space and after accessing the vision Appropriately, we fix the LMA in its anatomical position in the hypopharynx area. In this method, the patient does not undergo a laryngoscopy and the laryngoscope is used only to open the oral space and have a better view.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Ashayer hospital

Full name of responsible person

Aram Azizi Yousefvand

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No 36, Saba street,Keyo squire

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Khoram-Abad University of Medical Sciences

Full name of responsible person

Dr Behrooz Farzan

Street address

Lorestan University of Medical Sciences,Kmalvand

City

Khorramabad,

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Lorestan

Postal code

6813833946

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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

Khoram-Abad 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

Khoram-Abad University of Medical Sciences

Full name of responsible person

Aram Azizi

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after de-identifying individuals.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

University researchers

Under which criteria data/document could be used

Scientific use

From where data/document is obtainable

Lorestan University of Medical Sciences website

What processes are involved for a request to access data/document

Clear request of the applicant on the website of Lorestan

University of Medical Sciences to access the data and then review the request by the research assistant within

2 weeks and then allow access to the data.
Comments