Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of weight methods and anthropometric measurement of Hyocricoid Distance in predicting the appropriate size of Laryngeal Mask Airway in patients airway management

Protocol summary

Study aim

Comparison of the effect of choosing the size of LMA based on HCD with the standard method in the incidence of complications

Design

A randomized clinical trial, triple blind, with control group on 100 patients, which Random Generator software will be used for randomization

Settings and conduct

All eligible patients referred to Imam Hossein hospital who must undergo eye surgery and general anesthesia by LMA are considered for the study. Patients who consent to enter the study with ASA I-II, age over 18 years and no contraindications for LMA implantation will be included in the study. These patients are subjected to neck anthropometric measurements by a fabric graduated ruler. With these calculations, the amount of CMD, HCD and TMD will be recorded with a centimeter scale and two decimal places. Then the patients will be divided into one of the weight groups (W) or HCD using Random Generator software. The person performing the airway management is blinded to the group. All patients were anesthesized using 2 µ/kg fentanyl, 20 mg lidocaine, 1.5 mg/kg propofol, and 25 mg atracurium and underwent propofol infusion at a dose of 100-200 µ/k/min. After the placement of LMA and two hours after the patient wakes up, the evaluation regarding airway complications is done by a person who is blinded to the group.

Participants/Inclusion and exclusion criteria

All eligible patients referred to Imam Hossein hospital who for any reason must undergo eye surgery and general anesthesia by LMA are considered for the study.

Intervention groups

In the control group, LMA size will be selected based on weight, and in the intervention group, based on Hyocricoid Distance.

Main outcome variables

The success rate of LMA implantation based on effective ventilation and maximum expiratory pressure The rate of complications of LMA insertion such as sore throat, dry throat and dysphagia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231022059807N1**
Registration date: **2023-11-13, 1402/08/22**
Registration timing: **prospective**

Last update: **2023-11-13, 1402/08/22**
Update count: **0**

Registration date

2023-11-13, 1402/08/22

Registrant information

Name

Ardeshir Tajbakhsh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7343 0000

Email address

ardeshir.tajbakhsh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-22, 1402/09/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of weight methods and anthropometric measurement of Hyocricoid Distance in predicting the appropriate size of Laryngeal Mask Airway in patients airway management

Public title
Selecting Appropriate LMA
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients under general anesthesia by LMA Age above 18 years Absence of contraindications for LMA insertion ASA Class I-II
Exclusion criteria:
Lack of consent to enter the study
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization will be done with the help of Random Generator Android version. The first group will be measured by weight method and the second group will be choosing the size of LMA based on Hyocricoid Distance. This software displays the number one or two, and for each patient, a number 1 or 2 is taken from this software and assigned to the appropriate group.
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, a person outside of the study will randomly (by use of software) assign a patient to a group and determines the size of the patient's LMA. A fixed person will insert the LMA according to the announced number, without knowing the patient's group. The third person will record the complications after the LMA insertion without knowing the patient's group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of schol of medicine-Shahid Beheshti University of Medical Sciences
Street address
Valenjak Street, Faculty of Medicine, Shahid Beheshti University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1985717443
Approval date
2023-09-26, 1402/07/04
Ethics committee reference number
IR.SBMU.MSP.REC.1402.359

Health conditions studied

1

Description of health condition studied
Sore throat caused by LMA insertion
ICD-10 code
T88.5
ICD-10 code description
Other complications of anaesthesia

Primary outcomes

1

Description
Comparison of the effect of LMA size selection based on HCD with the standard method (based on weight) on the success rate of positive pressure ventilation
Timepoint
Measurement of airway pressure and the shape of the respiratory return curve after LMA implantation
Method of measurement
Fabius model anesthesia machine

2

Description
The rate of complications of LMA implantation
Timepoint
Immediately after anesthesia and two hours after anesthesia
Method of measurement
Questionnaire and interview

Secondary outcomes

empty

Intervention groups

1

Description
Control group: selection of LMA size based on weight
Category
Treatment - Devices

2

Description
Intervention group: selection of LMA size based on HCD
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein (AS) Hospital
Full name of responsible person
Ardeshir Tajbakhsh
Street address
Shahid Madani St
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
ardeshir.tajbakhsh@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Valenjak Faculty of Medicine, Shahid Beheshti University of Medical Sciences
City
tehran
Province
Tehran
Postal code
1985717443
Phone
+98 21 2243 9783
Email
ardeshir.tajbakhsh@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ardeshir Tajbakhsh
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Madani Street, Imam Hossein (AS) Hospital
City
Tehran
Province
Tehran
Postal code
1617763141
Phone
+98 21 7343 0000
Email
ardeshir.tajbakhsh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Ardeshir Tajbakhsh
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address

Shahid Madani Street, Imam Hossein (AS) Hospital

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 6343 0000

Email

ardeshir.tajbakhsh@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ardeshir Tajbakhsh

Position

Assistant Professor of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Imam Hossein General Hospital, Shahid Madani Street

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Fax

Email

ardeshir.tajbakhsh@gmail.com

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 collected deidentified IPD

When the data will become available and for how long

Access starts one month after results are published

To whom data/document is available

The data will be available to all applicants.

Under which criteria data/document could be used

The data will be available for scientific use only

From where data/document is obtainable

Applicants will apply to ardeshir.tajbakhsh@gmail.com.

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

The request was submitted to the research committee of Shahid Beheshti University of Medical Sciences' Department of Anesthesia, and if approved, it will be available after a week.

Comments