

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Determine the proper size of the laryngeal mask according to the weight and height criteria for women

Protocol summary

Study aim

Our purpose in this study is determine suitable method to select the laryngeal mask size in Iranian women

Design

In this research, 300 women patients referring to Khatam Hospital in Mashhad University of Medical Sciences and candidate for general anesthesia were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

This is a clinical study that was done in Khatam Hospital of Mashhad University of Medical Sciences in 2017.

Participants/Inclusion and exclusion criteria

In this study the patients who were 18 to 70 years old and had ASA physical status 1 to 3 undergoing general anesthesia, were entered in this study.

Intervention groups

The selection mask in control group was selected based on weight (according to the manufacturer's recommended weight of 30-50 kg: size 3, weight 50-70 kg: size 4, weight 70-90 kg: size 5) and intervention group Intervention was selected based on height (Height below 160 cm: size 3, height 160 cm: size 4) ,respectively.

Main outcome variables

Determine the appropriate classic LMA; Determine the rate of LMA complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170216032604N2**

Registration date: **2018-04-01, 1397/01/12**

Registration timing: **retrospective**

Last update: **2018-04-01, 1397/01/12**

Update count: **0**

Registration date

2018-04-01, 1397/01/12

Registrant information

Name

ZOHREH roohandeh

Name of organization / entity

Mashhad univercity medicin center

Country

Iran (Islamic Republic of)

Phone

+98 51 3606 1939

Email address

rouhandehz931@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

mashhad university of medicine

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

2016-05-21, 1395/03/01

Actual recruitment end date

2017-05-22, 1396/03/01

Trial completion date

empty

Scientific title

Determine the proper size of the laryngeal mask according to the weight and height criteria for women

Public title

Determine the proper size of the laryngeal mask according to the weight and height criteria for women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Female age of 18 to 70 years General Anesthesia
Candidate for eye surgery

Exclusion criteria:

BMI>40 mouth opening less than 2.5 cm symptomatic
hiatus hernia Esophageal reflux diseases recent infection
of upper respiratory track Sore throat
dysphonia/dysphagia

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **300**

Actual sample size reached: **300**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization is done by using closed envelopes. The researcher and the patient do not know the mask size selection criteria.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is double-blind study, that patients and researcher are unaware from type of selected mask. A pre-selected mask is given to them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical committee of Mashhad University of Medical Sciences

Street address

Daneshgah St, Ghoreish Building

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Approval date

2017-02-08, 1395/11/20

Ethics committee reference number

IR.mums.fm.REC.1395.561

Health conditions studied

1

Description of health condition studied

Selection size of Mask

ICD-10 code

T88.5

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Appropriate LMA

Timepoint

During LMA insertion, recovery and after 24 hours

Method of measurement

Interview based on incidence of complications

Secondary outcomes

1

Description

Complications of LMA

Timepoint

During the mask insertion

Method of measurement

Sore throat

Intervention groups

1

Description

Interventional group: selection size of LMA is based on height

Category

Treatment - Devices

2

Description

Control group: selection size of LMA is based on weight

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatamolania Hospital

Full name of responsible person

Zohreh Roohandeh
Street address
Taghiabad Square , Imam Reza (AS) Hospital,
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Z_roohandeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Mashhad University of
Medical Sciences
Full name of responsible person
Mahyar Mirheidari
Street address
Mashhad University of Medical Sciences; International
Offic Administration Center (Qoreishi Building) ;
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9137913316
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ramresearch@mums.ac.ir

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, Mashhad 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
Mashhad University Medical Sciences
Full name of responsible person
Zohreh Roohandeh
Position
Consultant of anesthesia
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Assistant prof
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bameshkiar@mums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
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Zohreh Roohandeh

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Assistant

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Other areas of specialty/work

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Fax**Email**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Spss file

When the data will become available and for how long

2017-2018

To whom data/document is available

Mashhad University of Medical Sciences

Under which criteria data/document could be used

frequency

From where data/document is obtainable

Zohreh Rohandeh

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

sent an email to Zohreh Rohandeh email:

Z_roohandeh@yahoo.com

Comments