

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation and comparison of success rate in laryngeal mask implantation with three anterior airway maneuvers and classical method

Protocol summary

Study aim

Evaluation and comparison of success rate in laryngeal mask implantation with three anterior airway maneuvers and classical method

Design

Clinical trial with control group with parallel groups, phase 3 on 110 patients

Settings and conduct

This study is performed in Feyz Hospital in Isfahan. Patients are intubated in two ways and the success rate and complications in both groups will be evaluated and compared with each other.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 20 to 80 years, ASA class one and two, weight 40-80 kg, body mass index less than 35, mouth opening at least 25 mm. Exclusion criteria: mouth opening less than 25 mm, pregnancy, supraglottic anatomical abnormalities, neck extension limitation, cervical spine abnormality, dysphagia, sore throat

Intervention groups

Intervention group 1: In this group, patients undergo intubation through the laryngeal mask using three airway maneuvers from the front. After intubation, the success rate of intubation in patients as well as its complications such as laryngospasm are examined by an anesthesiologist. Intervention group 2: In this group, patients undergo intubation through the classic method. After intubation, the success rate of intubation in patients as well as its complications such as laryngospasm are examined by an anesthesiologist.

Main outcome variables

Success rate, complications of intubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046523N15**

Registration date: **2021-05-05, 1400/02/15**

Registration timing: **prospective**

Last update: **2021-05-05, 1400/02/15**

Update count: **0**

Registration date

2021-05-05, 1400/02/15

Registrant information

Name

Aryan Rafiee Zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3837 1582

Email address

rafieezadeh.a@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-09, 1400/02/19

Expected recruitment end date

2021-06-09, 1400/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of success rate in laryngeal mask implantation with three anterior airway maneuvers and classical method

Public title

laryngeal mask implantation with three anterior airway

maneuvers and classical method

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 to 80 years ASA classification I or II
Weight 40-80 kg Body mass index less than 35 Mouth opening at least 25 mm
Exclusion criteria:
Mouth opening less than 25 mm Pregnancy Supraglottic anatomical abnormalities Neck extension restrictions Cervical spine deformity Dysphagia Existence of sore throat

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
N/A

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 Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.MUI.MED.REC.1400.074

Health conditions studied

1

Description of health condition studied

Anesthesia with laryngeal mask

ICD-10 code

T88.4

ICD-10 code description

Failed or difficult intubation

Primary outcomes

1

Description

Success rate in intubation

Timepoint

After trying to intubate

Method of measurement

Examination

2

Description

Complications of intubation

Timepoint

After trying to intubate

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In this group, patients undergo intubation through the laryngeal mask using three airway maneuvers from the front. After intubation, the success rate of intubation in patients as well as its complications such as laryngospasm are examined by an anesthesiologist.

Category

Treatment - Other

2

Description

Intervention group 2: In this group, patients undergo intubation through the classic method. After intubation, the success rate of intubation in patients as well as its complications such as laryngospasm are examined by an anesthesiologist.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Feyz hospital

Full name of responsible person

Hamidreza Shetai

Street address

Feyz hospital, Feyz Ave., Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673118

Phone

+98 31 3668 0048

Email

hamidshetabi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673118

Phone

+98 31 3668 0048

Email

haghjoo.sh@med.mui.ac.ir

Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetai

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

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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 can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Isfahan University of Medical Sciences website

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments