

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of choosing the size of laryngeal mask based on width of tongue on ease of placement, effective ventilation and post-operative sore throat.

Protocol summary

Study aim

Effect of choosing the size of laryngeal mask based on width of tongue on ease of placement, effective ventilation and post-operative sore throat

Design

This study is a randomized clinical trial with control group. In this study, 60 patients according to randomized block design for gender, were selected in two parallel groups (intervention and control). Patients and the persons who collect information are unaware of the type of intervention.

Settings and conduct

This study is carried out in the operating room of the Koosar Hospital in Semnan. Patients are randomly assigned to one of the two groups, intervention (mask selection based on the width of the tongue) and the control (mask size selection based on the patient's weight). Then an experienced person, without being aware of how to choose a laryngeal mask, puts it for the patients and score the ease of placement of it. During surgery the effective ventilation were evaluated. After surgery, the patient's throat irritation score is completed by person who do not know the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18 years, Ability to communicate, ASA class I, II Exclusion criteria: Weight less than 30 kg, high risk for aspiration, difficult insertion tube with mallampati class IV, Abnormality in larynx

Intervention groups

Intervention group: Choosing the size of the laryngeal mask is based on the patient's tongue width. Control group: Choosing the size of the laryngeal mask is based on the patient's weight.

Main outcome variables

Ease of placement of laryngeal mask; Effective ventilation; Sore throat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110514006481N11**

Registration date: **2019-02-19, 1397/11/30**

Registration timing: **prospective**

Last update: **2019-02-19, 1397/11/30**

Update count: **1**

Registration date

2019-02-19, 1397/11/30

Registrant information

Name

Mohsen Soleimani

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 23 3365 4190

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soli257@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of choosing the size of laryngeal mask based on width of tongue on ease of placement, effective ventilation and post-operative sore throat.

Public title

Method of laryngeal mask size selection on post-operative sore throat

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Ability to communicate Length of surgery less than 2.5 hours American Society of Anesthesiologists (ASA) class I, II

Exclusion criteria:

Weight less than 30 kg High risk for aspiration Difficult insertion tube with mallampati class IV Abnormality in larynx

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done using stratified permuted block randomization. Patients are divided into two stratum of women and men. For each stratum, a separate random assignment continues to reach the sample size. For random assignment in each stratum, four blocks of (A, B), which include different states of test and control sequences (AABB, ABAB ...), are used. Block selection is done according to a random digits table.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, a person who places a laryngeal mask for patient, as well as the patients and a person who complete the questionnaire are not aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, 5th Km Damghan road.

City

Semnan

Province

Semnan

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3514753165

Approval date

2018-12-18, 1397/09/27

Ethics committee reference number

IR.SEMUMS.REC.1397.202

Health conditions studied

1

Description of health condition studied

Oedema of larynx

ICD-10 code

J38.4

ICD-10 code description

Oedema of larynx

Primary outcomes

1

Description

Sore throat

Timepoint

After waking up, 1 hour after surgery, 6 hours after surgery

Method of measurement

Numeric Rating Scale

Secondary outcomes

1

Description

Easy insertion of laryngeal mask

Timepoint

After insertion of laryngeal mask

Method of measurement

Visual Analogue Scale

2

Description

Effective ventilation

Timepoint

After insertion of laryngeal mask

Method of measurement

Measurement of expiratory air volume

Intervention groups

1

Description

Intervention group: For these patients, the laryngeal mask selection is performed by matching the largest mask width and the largest portion of the patient's tongue.

Category

Prevention

2

Description

Control group: For these patients, the laryngeal mask selection is performed by the patient's weight.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Koosar Hospital

Full name of responsible person

Dr Mohsen Soleimani

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Koosar hospital, Amin street, Basij Blvd.

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Sponsors / Funding sources

1

Sponsor

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Mohsen Soleimani

Position

Associate professor

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)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is not more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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