

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of postoperative respiratory complications of Laryngeal Mask Airway and Tracheal tube in candidates of prolonged ENT operations

Protocol summary

Summary

The main purpose of this study is to compare respiratory complications of tracheal tube and laryngeal mask airway after prolonged Ear, Nose, Throat surgeries. Candidates must not have any contraindication for using laryngeal mask airway and their surgery must not have any influence on postoperative respiratory complications. Candidates of prolonged (>2hours) ear, nose, throat surgery in Hazrat Rasol Medical Complex were the target population of our study. 171 patients of study were divided into two groups and in the first group laryngeal mask airway and in second group tracheal tube was used for airway control during surgery. The incidences of four postoperative complications: sore throat, hoarseness, cough and shortness of breath were recorded in immediate postoperative period and compared in the two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013102215108N1**

Registration date: **2014-01-03, 1392/10/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-01-03, 1392/10/13

Registrant information

Name

Reza Safaeian

Name of organization / entity

Iran University of medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

rezasafaa@hotmail.com

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research, Iran University of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2013-03-19, 1391/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of postoperative respiratory complications of Laryngeal Mask Airway and Tracheal tube in candidates of prolonged ENT operations

Public title

Comparison of postoperative respiratory complications of Laryngeal Mask Airway and Tracheal tube in candidates of prolonged ENT operations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA I and II patients; candidates for ENT surgeries of more than two hours duration; age more than 13y old; mallampati score of 1 or 2; no positive history of chronic or acute respiratory diseases or smoking; Exclusion criteria: Obese patients; pregnant women; patients with gastroesophageal reflux; patients with surgeries on throat and lower regions of respiratory system

Age

No age limit

Gender

Male

Phase

2-3

Groups that have been masked

No information

Sample sizeTarget sample size: **171****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research committee of Anesthesiology Department

Street address

Rasoul Akram Hospital

City

Tehran

Postal code**Approval date**

2012-01-21, 1390/11/01

Ethics committee reference number

ارسال میشود

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

Respiratory complications of airway control devices

ICD-10 code

S00-T98

ICD-10 code description

-injury, poisoning and certain other consequences of external causes

Primary outcomes**1****Description**

Sore Throat

Timepoint

2 hours after operation

Method of measurement

Asking from the patient

2**Description**

Hoarsness

Timepoint

2 hours after operation

Method of measurement

Asking from the patient

3**Description**

Cough

Timepoint

2 hours after operation

Method of measurement

Asking from the patient

4**Description**

Shortness of breath

Timepoint

2 hours after operation

Method of measurement

Asking from the patient and direct observation

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Laryngeal Mask Airway will be used.

This was done using classic method without any introducer by Anesthesiology specialist trainees

Category

Treatment - Devices

2**Description**

Control group: Endotracheal intubation by anesthesiology specialist trainees

Category

Treatment - Devices

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoul Akram Hospital

Full name of responsible person

Dr Reza Safaeian

Street address

Niayesh St., Satarkhan St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor For research, Iran university of Medical Sciences

Full name of responsible person

Dr Motavalian

Street address

Hemmat Freeway, Next to Milad tower

City

Tehran

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, Iran university of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Safaeian

Position

Faculty member/ Anesthesiologist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty