

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effects and side effects of LMA and tracheal tube in children under general anesthesia for cochlear implantation.

Protocol summary

Summary

Laryngoscopy and tracheal intubation may cause hemodynamic changes, cartilage dislocation and sore throat and requires some levels of muscle relaxation which could interfere with nerve monitoring in cochlear implant surgery. On the other hand, LMA does not require muscle relaxation as deep as needed for tracheal tubes. It also might cause less hemodynamic changes in patients. Objectives: comparing the effects and side effects of LMA and laryngeal tube for airway management in children candidate for cochlear implantation, concerning the airway pressure, arterial blood O2 saturation, end tidal CO2, cough, spasm, apnea, sore throat, vomiting and dysrhythmia. Design: this study is a randomized, single-blinded, mono center clinical trial Setting and Conduct: Patients divide randomly into two groups of LMA and Tracheal Tube. Anesthesia technique would be the same in both groups. During surgery, arterial O2 saturation, end-tidal CO2, airway pressure and pulse rate would be monitored in both groups and would be compared. Moreover, degree of bleeding and surgeon's satisfaction of surgical field would be compared. In post operative period presence or absence of cough, spasm, apnea, vomiting, sore throat and dysrhythmia would be sought and compared too. Patients and Criteria: Sixty deaf children between 3 to 17 years old in ASA classification I and II candidate for cochlear implant, Exclusion criteria would be upper respiratory tract infection and any findings accounting for difficult airway Main outcome: arterial O2 saturation, end-tidal CO2, airway pressure, pulse rate, cough, spasm, apnea, sore throat, vomiting and dysrhythmia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011512134N1**

Registration date: **2013-01-20, 1391/11/01**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-01-20, 1391/11/01

Registrant information

Name

Kamran Mottaghi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 5542 4040

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k_mottaghi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences , Loghman Hospital

Expected recruitment start date

2013-03-01, 1391/12/11

Expected recruitment end date

2013-09-01, 1392/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects and side effects of LMA and tracheal tube in children under general anesthesia for cochlear implantation.

Public title

Is LMA applicable in cochlear implant?

Purpose

Other

Inclusion/Exclusion criteria

Inclusion: elective cochlear implant surgery; ASA class I,II; age between 3-17 year; parental consent. Exclusion criteria: upper airway infection; finding of difficult airway.

Age

From **3 years** old to **17 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Patients are not aware of the details of the study but they do not know which patient is in which group. On the other hand, patients are mostly small children who are not familiar with anesthetic process. So we believe that both the parents and patients are blind about the study. All the parents would sign the consent.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Tabnak St, Evin, Chamran Highway

City

Tehran

Postal code

Approval date

2012-05-16, 1391/02/27

Ethics committee reference number

308/1539

Health conditions studied

1

Description of health condition studied

cochlear implant

ICD-10 code

Z96.2

ICD-10 code description

cochlear implant, Presence of otological and audiological implants

2

Description of health condition studied

Hearing Loss, Deafness

ICD-10 code

H91.9

ICD-10 code description

Hearing Loss, Deafness

Primary outcomes

1

Description

Airway Pressure

Timepoint

15 minutes

Method of measurement

mm Hg

2

Description

End Tidal CO2

Timepoint

15 minutes

Method of measurement

mm Hg, Capnography

3

Description

Arterial O2 Saturation SaO2

Timepoint

15 minutes

Method of measurement

percent (%), Pulseoximetry

4

Description

Pulse Rate

Timepoint

15 minutes

Method of measurement

Beat per Minute, Pulseoximetry, Electrocardiography

5

Description

Sore throat

Timepoint

In Post Anesthesia Care Unit and 24 hours post operation

Method of measurement

Asking patients, Visual Analog Scale

6**Description**

Cough

Timepoint

In Post Anesthesia Care Unit and 24 hours post operation

Method of measurement

Observation, Absent or Present

7**Description**

Bronchospasm/Wheezing

Timepoint

In Post Anesthesia Care Unit

Method of measurement

Physical Examination, Auscultation, Absent/Present

8**Description**

Laryngospasm/ Desaturation

Timepoint

In Post Anesthesia Care Unit

Method of measurement

Physical Examination, Pulseoximetry, Absent/Present

9**Description**

Vomiting

Timepoint

In Post Anesthesia Care Unit

Method of measurement

Observation, Absent or Present

10**Description**

Cardiac Dysrhythmia

Timepoint

During Operation and in Post Anesthesia Care Unit

Method of measurement

Electrocardiogram, Absent/Present

Secondary outcomes**1****Description**

Bleeding during surgery

Timepoint

15 minutes

Method of measurement

Surgical field observation (grade 1 to 5)

2**Description**

Surgeon's Satisfaction of surgical Field

Timepoint

15 minutes

Method of measurement

Asking Surgeon (grade 1 to 3)

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

Intervention group: airway management with Laryngeal Mask Airway (LMA) without laryngoscopy at induction

Category

Other

2**Description**

Control group: airway management with tracheal tube after laryngoscopy with McGill blade at induction

Category

Other

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

Loghman Hospital

Full name of responsible person

Kamran Mottaghi

Street address

Loghman Hospital, Makhsous St, Kamali St, Kargar Ave,

City

Tehran

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shahid Beheshti University of Medical Sciences , Loghman Hospital

Full name of responsible person

Alireza Salimi

Street address

Loghman Hospital, Makhsous St, Kamali St, Kargar Ave

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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

Vice chancellor for research, Shahid Beheshti University of Medical Sciences , Loghman Hospital

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Kamran Mottaghi

Position

Anesthesiologist, Assistant Professor

Other areas of specialty/work

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City

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