Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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, degreel 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

Email address

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 laryngoscpy 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
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, 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

Street address

Loghman Hospital, Makhsous St, Kamali St, Kargar Ave

City

Tehran

Postal code

13336-31151

Phone

+98 21 5542 4040

Fax

+98 21 5542 4040

Email

k_mottaghi@sbmu.ac.ir; kmrnmtghi@yahoo.com

Web page address

Person responsible for scientific 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

Street address

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Fax

+98 21 5542 4040

Email

k_mottaghi@sbmu.ac.ir; kmrnmtghi@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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+98 21 5542 4040

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k_mottaghi@bmu.ac.ir; kmrnmtghi@yahoo.com

Web page address

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