

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Oct 2026

Tracheal intubation without muscle relaxant with Propofol or Sevoflurane in 2-7 year old children undergoing ear-nose-throat surgery

Protocol summary

Summary

Purpose: To compare intubation conditions and cardiovascular changes following induction of anesthesia and tracheal intubation in patients receiving either lidocaine-remifentanyl-propofol or lidocaine-remifentanyl-sevoflurane prior to induction. Methods: In a randomized, double-blind study 75 healthy children patients with these exclusion criteria: 1) cardiac disease, 2) asthma and any other pulmonary disease, 3) gastroesophageal reflux, 4) morbid obesity (BMI>30), 5) difficult tracheal intubation were assigned to one of two groups: lidocaine 1.5 mg/kg, remifentanyl 2 µg/kg and propofol 2 mg/kg (Group P) or lidocaine 1.5 mg/kg, remifentanyl 2 µg/kg and sevoflurane (Group S). Then laryngoscopy and tracheal intubation were attempted at BIS 40-50. Intubation conditions were assessed as excellent, good or poor on the basis of ease of ventilation, position of the vocal cords, and patient's response to intubation and slow inflation of the tracheal cuff. The mean arterial pressure (MAP) and heart rate (HR) were measured before anesthetic agent administration, immediately after tracheal intubation, and five minutes after intubation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102135822N1**

Registration date: **2011-03-14, 1389/12/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-03-14, 1389/12/23

Registrant information

Name

Valiollah Hassani

Name of organization / entity

Department of Anesthesiology, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran university of medical sciences

Expected recruitment start date

2010-01-11, 1388/10/21

Expected recruitment end date

2011-01-11, 1389/10/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Tracheal intubation without muscle relaxant with Propofol or Sevoflurane in 2-7 year old children undergoing ear-nose-throat surgery

Public title

Tracheal intubation without muscle relaxant

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria): 1) age 2-7 years, 2) ENT & Eye surgery candidate. Exclusion Criteria): 1) cardiac disease, 2) asthma and any other pulmonary disease,

3)gastroesophageal reflux, 4)morbid obesity (BMI>30) ,
5)difficult tracheal expected intubation.

Age

From **2 years** old to **7 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **75**

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

Ethics committee of Tehran (previous Iran) university
of medical sciences

Street address

Hemmat highway, between Sheikh Fazlollah and
Chamran

City

Tehran

Postal code

Approval date

2009-12-07, 1388/09/16

Ethics committee reference number

1485631

Health conditions studied

1

Description of health condition studied

general anesthesia for ear-nose-throat surgery

ICD-10 code

H65.2

ICD-10 code description

Chronic serous otitis media

Primary outcomes

1

Description

the ease with which the patient is intubated

Timepoint

at the time of intubation (start of anesthesia)

Method of measurement

an scoring system measuring the ease/difficulty of
intubation (scored by the anesthesiologist)

Secondary outcomes

1

Description

the ease of mask ventilation

Timepoint

after induction of general anesthesia

Method of measurement

an scoring system measuring the ease/difficulty of mask
ventilation

2

Description

vocal cord position

Timepoint

at the time of tracheal intubation

Method of measurement

an scoring system measuring the vocal cord position by
anesthesiologist

3

Description

the ease of laryngoscopy

Timepoint

at the time of laryngoscopy

Method of measurement

an scoring system measuring the ease/difficulty of
laryngoscopy by anesthesiologist

4

Description

coughing

Timepoint

at the time of tracheal intubation

Method of measurement

an scoring system measuring the coughing by
anesthesiologist

5

Description

blood pressure changes

Timepoint

before and at the time of intubation,5 min after
intubation

Method of measurement

non invasive blood pressure monitoring

6

Description

heart rate changes

Timepoint

before and at the time of intubation, 5 min after intubation

Method of measurement

ECG monitoring

Intervention groups

1

Description

intervention group: lidocaine 1.5 mg/kg, remifentanyl 2 µg/kg and propofol 2mg/kg were injected intravenously

Category

Treatment - Drugs

2

Description

lidocaine 1.5 mg/kg intravenously and remifentanyl 2 µg/kg intravenously injected and sevoflurane 3%MAC inhalationally was added

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul Akram hospital of tehran university of medical sciences

Full name of responsible person

Dr Valiollah Hassani

Street address

Niayesh street, Sattarkhan street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tehran University of Medical Sciences

Full name of responsible person

Doctor Akbar Fotouhi

Street address

Hemmat highway, between Sheikh Fazlollah and Chamran

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, Tehran 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

Tehran university of medical sciences

Full name of responsible person

Dr. Nazanin Mirabi

Position

anesthesiology assistant

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

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Web page address	<i>empty</i>
Person responsible for updating data	Statistical Analysis Plan <i>empty</i>
Contact	Informed Consent Form <i>empty</i>
Sharing plan	Clinical Study Report <i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Analytic Code <i>empty</i>
Study Protocol	Data Dictionary <i>empty</i>