

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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-remifentanil-propofol or lidocaine-remifentanil-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, remifentanil 2 µg/kg and propofol 2 mg/kg (Group P) or lidocaine 1.5 mg/kg, remifentanil 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6650 9059

##### Email address

valiollah\_hassani@yahoo.com

##### 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

#### Street address

Rasul Akram complex, Niayesh street, Sattarkhan street

#### City

Tehran

#### Postal code

#### Phone

+98 21 6651 6001

#### Fax

#### Email

nazaninmirabi@yahoo.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran university of medical sciences

#### Full name of responsible person

Dr. Valiollah Hassani

#### Position

professor of anesthesiology

#### Other areas of specialty/work

#### Street address

Rasul Akram Complex, Niayesh street, Sattarkhan street

#### City

Tehran

#### Postal code

#### Phone

+98 21 6651 6001

#### Fax

#### Email

v-hassani@sina.ac.ir

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