

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparison the effect of propofol and sodium thiopental on post-extubation laryngospasm in patients undergoing tonsillectomy.

Protocol summary

Summary

1-Introduction and background: One of the important complications of tonsillectomy is laryngospasm which leads to airway obstruction, arterial hypoxemia and hypercarbia. 2-Objective: Comparison of the effect of propofol and sodium thiopental as an induction agent on incidence and intensity of laryngospasm after extubation in tonsillectomy. 3- Design: Double blind prospective analytic study (clinical trial), 4- Setting and conduct: 60 paediatric patients who had been scheduled for tonsillectomy were randomly divided into two equal groups. Methods of anesthesia were the same for the two groups except in the induction of anesthesia. One group received sodium thiopental and the other group received propofol. At the end of the operation patients were extubated when they returned to their spontaneous breathing with adequate tidal volume. The occurrence and intensity of laryngospasm were then compared. Inclusion criteria: Children aged 3 to 12 years old and ASA class 1. Exclusion criteria: 1- History of common cold and sore throat in the 5 weeks prior to the study 2- intubation attempt failed twice or more. (6) Intervention: In control group (Thiopental), for premedication used Diazepam 0.05 mg/kg and Fentanyl 1microgram/kg and atropine 20microgram/kg. For induction of anesthesia in this group used Thiopental 5mg/kg. In the intervention group (propofol), for premedication used Diazepam 0.05 mg/kg and Fentanyl 1microgram/kg and atropine 20 microgram/kg. For induction of anesthesia in this group used Propofol 2.5mg/kg (7) main outcome measure (variables) is laryngospasm

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201008164578N1**

Registration date: **2010-11-07, 1389/08/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-11-07, 1389/08/16

Registrant information

Name

Farshid Rahimibashar

Name of organization / entity

Hamedan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Qazvin university of medical sciences

Expected recruitment start date

2004-04-20, 1383/02/01

Expected recruitment end date

2004-11-20, 1383/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of propofol and sodium thiopental on post-extubation laryngospasm in patients undergoing tonsillectomy.

Public title

The effect of general anesthesia on tonsillectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children in 3-12 years old and ASA class 1
exclusion criteria: 1- History of common cold and sore throat in the 5 weeks prior to the study 2- History of corticosteroid usage. 3- The presence of upper and lower respiratory tract infection. 4- The presence of abnormality in the airways. 5- intubation attempt failed twice or more

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Qazvin University of Medical Sciences

Street address

Bahonar Boulevard, Qazvin University of Medical Sciences -

City

Qazvin

Postal code

59811-34197

Approval date

2004-04-13, 1383/01/25

Ethics committee reference number

19

Health conditions studied

1

Description of health condition studied

Enlargment of tonsils

ICD-10 code

J35.1

ICD-10 code description

Hypertrophy of tonsils

2

Description of health condition studied

General Anesthesia in tonsillectomy

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Laryngospasm

Timepoint

Laryngospasm is visualized in the end of surgery and after extubation of patient

Method of measurement

Patient were divided in four groups: 1-without laryngospasm 2-mild laryngospasm 3-moderate laryngospasm 4-sever laryngospasm

Secondary outcomes

empty

Intervention groups

1

Description

In control group (Thiopental), for premedication used Diazepam 0.05 mg/kg and Fentanyl 1microgram/kg and atropine 20 microgram/kg. For induction of anaesthesia in this group used Thiopental 5mg/kg

Category

Treatment - Drugs

2

Description

In intervention group (propofol), for premedication used Diazepam 0.05 mg/kg and Fentanyl 1microgram/kg and atropine 20 microgram/kg. For induction of anaesthesia in this group used Propofol 2/5mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghods hospital

Full name of responsible person

Dr. seyed Abbas Hosseini Jahromi

Street address

Ghods hospital-Shahid Beheshti Blvd-Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin university of medical sciences-vice chancellor for research

Full name of responsible person

Dr.Saeid Asefzade

Street address

Bahonar Boulevard,

City

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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

Qazvin university of medical sciences-vice chancellor for research

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Seyed Abbas Hosseini Jahromi

Position

Assistant Professor/Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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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