

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 811264002151

###### Email address

f.rahimi@umsh.ac.ir

##### 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**

Qazvin

**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**

**Street address**

Shahid Rajaei hospital, end of Garrison Avenue

**City**

Qazvin

**Postal code**

3413996134

**Phone**

+98 28 1333 5800

**Fax**

+98 28 1332 0105

**Email**

papaya812002@yahoo.com; hosrajaee@qums.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr Seyede Masoume Hosseini Valalmi

**Position**

Assistant Professor/Anesthesiologist

**Other areas of specialty/work**

**Street address**

Shahid Rajaei hospital- end of Garrison Avenue

**City**

Qazvin

**Postal code**

3413996134

**Phone**

+98 28 1333 5800

**Fax**

+98 28 1332 0105

**Email**

parspaya872008@yahoo.com; hosrajaee@qums.ac.ir

**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*