

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jun 2026

Comparing the effect of propofol and thiopental on emergence agitation after anesthesia with isoflurane in Children undergoing adenotonsillectomy surgery.

Protocol summary

Summary

The aim of this study was to compare the effect of thiopental and propofol on the emergence agitation due to anesthesia maintained by isoflurane. This single blind randomized clinical trial study was done in valiasr hospital of Birjand University of Medical Sciences on 40 patients between 3 to 9 years who were scheduled for adenotonsillectomy surgery under general anesthesia, allocated in two groups according to the type of hypnotic used for induction of anesthesia, thiopental 5 mg/kg, propofol 2 mg/kg. In each of two groups regardless of the type of hypnotic fentanyl 2 µg/kg and atracurium 0.5 mg/kg were administered and isoflurane 1.5% were used for maintenance of anesthesia. Emergence agitation was compared between two groups according to modified objective of pain score (MOPS) at 15, 30 minutes and 2, 4, 6 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016060121383N6**

Registration date: **2016-07-16, 1395/04/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-07-16, 1395/04/26

Registrant information

Name

Amir Saber Tanha

Name of organization / entity

Birjand University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 56 3243 2778

Email address

dr.saber@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Birjand University of Medical Sciences.

Expected recruitment start date

2016-05-24, 1395/03/04

Expected recruitment end date

2016-08-25, 1395/06/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of propofol and thiopental on emergence agitation after anesthesia with isoflurane in Children undergoing adenotonsillectomy surgery.

Public title

The effect of propofol on isoflurane induced emergence agitation.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all patients aged 3 to 9 years who were scheduled for adenotonsillectomy surgeries under general anesthesia maintained by isoflurane. Exclusion criteria: all patients with history of allergic reactions to egg or soy beans; positive familial history of malignant hyperthermia; psychological disorders or any history of

usage of sedative or hypnotic drugs; attention deficit hyperactivity disorder.

Age

From **3 years** old to **9 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This study was randomized by table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Ghafari Street, Birjand.

City

Birjand

Postal code

9717853577

Approval date

2016-05-23, 1395/03/03

Ethics committee reference number

lr.bums.1395.9

Health conditions studied

1

Description of health condition studied

Emergent agitation

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

Agitation

Timepoint

15, 30 minutes and 2, 4, 6 hours after surgery

Method of measurement

Modified Objective Pain Score (MOPS)

Secondary outcomes

empty

Intervention groups

1

Description

Administration Of propofol 2mg/kg

Category

Prevention

2

Description

Administration Of thiopental 5mg/kg

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital of Birjand University of Medical Sciences

Full name of responsible person

Dr. Amir Saber Tanha

Street address

Valiasr hospital, Ghafari Street, Birjand

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Birjand University of Medical Sciences

Full name of responsible person

Dr. Asghar Zarban

Street address

Birjand University of Medical Sciences, Ghafari Street, Birjand.

City

Birjand

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 of Birjand 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**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Amir Saber Tanha

Position

Assistant professor of anesthesia

Other areas of specialty/work**Street address**

Birjand University of Medical Sciences, Ghafari Street, Birjand.

City

Birjand

Postal code**Phone**

+98 56 3243 2778

Fax**Email**

amirsaber63@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Amir Saber Tanha

Position

Assistant professor of anesthesia

Other areas of specialty/work**Street address**

Birjand University of Medical Sciences, Ghafari Street, Birjand

City

Birjand

Postal code**Phone**

+98 56 3243 2778

Fax**Email**

amirsaber63@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Birjand University of Medical Sciences

Full name of responsible person

Dr. Amir Saber Tanha

Position

Assistant professor of anesthesia

Other areas of specialty/work**Street address**

Birjand University of Medical Sciences, Ghafari Street, Birjand

City

Birjand

Postal code**Phone**

00

Fax**Email****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*