Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 adenotonsilectomy 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 fentanyle 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)

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+98 56 3243 2778

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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
۹۷۱۷۸۵۳۵۷۷

Approval date
2016-05-23, 1395/03/03

Ethics committee reference number
Ir.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
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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