Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Post-anesthetic Administration of Propofol and Midazolam in Prevention of Post-extubation Agitation after Isoflurane Anesthesia in Children undergoing Tonsillectomy

Protocol summary

Study aim
Comparison of post-anesthetic administration of propofol and midazolam in prevention of post-extubation agitation after Isoflurane anesthesia in children undergoing tonsillectomy

Design
Randomized, controlled, parallel group trial with blinded outcome assessment. Randomization was centralized with simple randomization with random number tables

Settings and conduct
Patients, researchers responsible for data collection and analyses are blind to the groups allocation

Participants/Inclusion and exclusion criteria
Inclusion criteria: children aged 3 to 15 years old, anesthesia risk classification of ASA class of I or II, and obtaining written consent from the parents; Exclusion criteria: no consent from the parent, children with cognition diseases, children with delayed growth factors

Intervention groups
Ninety patients are randomly divided into two intervention groups and one control group (each 30 cases). In the Intervention group (1), Immediately before termination of isoflurane administration, midazolam with 0.03 mg/kg dosage is administered. In the Intervention group (2), Immediately before termination of isoflurane administration, midazolam with 1 mg/kg dosage is administered. In the control group, immediately before termination of isoflurane administration, normal saline is administered

Main outcome variables
The level of agitation is assessed according to PAED scale at 5, 10, 20 and 30 minutes after the drug administration

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180811040764N1**
Registration date: **2018-08-20, 1397/05/29**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-20, 1397/05/29**
Update count: **0**

Registration date
2018-08-20, 1397/05/29

Registrant information

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Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-08-08, 1397/05/17

Expected recruitment end date
2018-11-08, 1397/08/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Post-anesthetic Administration of Propofol

and Midazolam in Prevention of Post-extubation Agitation after Isoflurane Anesthesia in Children undergoing Tonsillectomy

Public title
Propofol and Midazolam Effects on Agitation Prevention after Isoflurane Anesthesia in Children Candidate of Surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 3 to 15 years old American Society of Anesthesiologists (ASA) classification I, II Obtaining written consent form from parent
Exclusion criteria:
Children with cognition diseases Children with delayed growth factors
Age
From **3 years** old to **15 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with random number tables
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients, responsible for collecting data, data analyzer
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz University of Medical Sciences
Street address
Golestan Blvd., Research deputy, Ahvaz Jundishapur University Of Medical Sciences
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Province
Khouzestan
Postal code
6135715794
Approval date
2018-02-03, 1396/11/14
Ethics committee reference number
IR.AJUMS.REC.1396.948

Health conditions studied

1

Description of health condition studied
tonsillitis
ICD-10 code
J35
ICD-10 code description
Chronic diseases of tonsils and adenoids

Primary outcomes

1

Description
Agitation level
Timepoint
5, 10, 20 and 30 minutes after injection medication
Method of measurement
Pediatric Anesthesia Emergence Delirium (PAED) Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (1): Immediately before termination of isoflurane administration, midazolam with 0.03 mg/kg dosage is administered, Intervention group (2): Immediately before termination of isoflurane administration, midazolam with 1 mg/kg dosage is administered.
Category
Treatment - Drugs

2

Description
Control group: Immediately before termination of Isoflurane administration, normal saline is administered
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital, Ahvaz Jundishapur University of Medical Sciences

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Sponsors / Funding sources

1

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Grant name

Grant code / Reference number
PAIN-9612

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Ahvaz University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz University of Medical Sciences

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Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable