

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 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

Name

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Name of organization / entity

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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

Khuzestan

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

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

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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

Full name of responsible person

Masooome Mahdavi Rad

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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