

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of effects of Propofol and Ketofol (Ketamine-Propofol mixture) on Emergence Agitation in Children undergoing Tonsillectomy

Protocol summary

Summary

Objectives: the aim of this study is to compare the effect of propofol and ketofol (ketamine-propofol mixture) on EA in children . Design: randomized clinical trial Setting and conduct: in this study, 87 ASA (American Society of Anesthesiologist) class I and II, candidate for elective tonsillectomy in Valiasr hospital of zanzan, will divide into two groups.Inclusion criteria are: age between 3-12 years old; ASA class I and II and elective tonsillectomy. Exclusion criteria are: increased intracranial or intraocular pressure; porphyria; hepatic dysfunction; allergy to eggs or soybeans; history of psychiatric disorder; upper respiratory tract infection. Intervention: control group, n=44, will receive infusion of propofol 100µg/kg/min and intervention group, n= 43 will receive infusion of ketamine 25µg/kg/min + propofol 75µg/kg/min. At the end of surgery and after transmission to recovery room,on arrival time and after 10 and 30 min stay in recovery, gitation score will evaluated by Pediatric Anesthesia Delirium Emergence (PAED). Main outcome measure is postanesthesia agitation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017082829414N3**

Registration date: **2017-10-29, 1396/08/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-29, 1396/08/07

Registrant information

Name

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Name of organization / entity

Zanzan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanzan University of Medical Sciences, Dr Alireza Shogli

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-02-19, 1396/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effects of Propofol and Ketofol (Ketamine-Propofol mixture) on Emergence Agitation in Children undergoing Tonsillectomy

Public title

Effects of Propofol and Ketofol (Ketamine-Propofol mixture) on Emergence Agitation in Children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria are: age between 3-12 years old; ASA class I and II and elective tonsillectomy. Exclusion criteria are: increased intracranial or intraocular pressure; porphyria; hepatic dysfunction; allergy to eggs or

soybeans; history of psychiatric disorder; upper respiratory tract infection.

Age

From **3 years** old to **12 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **87**

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

Ethics Committee of Zanzan univercity of medical sciences

Street address

Zanzan University of Medical Sciences, Azadi Avenue

City

Zanzan

Postal code

Approval date

2014-09-23, 1393/07/01

Ethics committee reference number

IR.ZUMS.REC.1393.70

Health conditions studied

1

Description of health condition studied

postanesthesia agitation

ICD-10 code

XXI

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes

1

Description

Postanesthesia agitation

Timepoint

On arrival and after 10 and 30 min stay in recovery

Method of measurement

Pediatric Anesthesia Emergence Delirium

Secondary outcomes

1

Description

Laryngospasm

Timepoint

First 30 min in recovery

Method of measurement

By anesthesiologist

2

Description

Bronchospasm

Timepoint

First 30 min in recovery

Method of measurement

By anesthesiologist

3

Description

Patients requiring sedative

Timepoint

First 30 min in recovery

Method of measurement

By anesthesiologist

4

Description

Bleeding

Timepoint

First 30 min in recovery

Method of measurement

By anesthesiologist

Intervention groups

1

Description

Group p, control group, n=44, infusion of propofol 100µg/kg/min

Category

Treatment - Drugs

2

Description

Group k or ketofol , intervention group, n= 43:infusion of ketamine 25µg/kg/min + propofol 75µg/kg/min

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr. Ali Esmaeli

Street address

Valiasr Hospital, Fazlolah noori avenue

City

Zanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Zanjan University of Medical Sciences

Full name of responsible person

Dr Alireza Shogli

Street address

Zanjan University of Medical Sciences, Azadi avenue

City

Zanjan

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, Zanjan 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

Zanjan University of Medical Sciences

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Ali Esmaeli

Position

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Other areas of specialty/work

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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