Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 zanjan, 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

Zanjan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan 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 Zanjan univercity of medical sciences

Street address
Zanjan University of Medical Sciences, Azadi Avenue

City
Zanjan

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

Treatment - Drugs

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
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Zanjan University of Medical Sciences, Azadi avenue
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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
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Person responsible for updating data

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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