

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 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 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 be 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**

Vahideh Rashtchi

##### Name of organization / entity

Zanzan university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 341 1683

##### Email address

rashtchi@zums.ac.ir

##### 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 Zanjan university 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

**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

**Full name of responsible person**

Ali Esmaeli

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Valiasr Hospital, Valiasr St.

**City**

Zanjan

**Postal code**

**Phone**

+98 24 3302 3270

**Fax**

**Email**

ALI.ESMAEILI26@YAHOO.COM

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Ali Smaelie

**Position**

Anistesthesiolog

**Other areas of specialty/work**

**Street address**

Valiasr Hospital

**City**

Zanjan

**Postal code**

**Phone**

+98 24 3302 3270

**Fax**

**Email**

ALI.ESMAEILI26@YAHOO.COM

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Zanjan University of Medical Sciences

**Full name of responsible person**

Vahideh Rashtchi

**Position**

Anesthesiologist

**Other areas of specialty/work**

**Street address**

Musavi Hospital, Gavazang Avenue

**City**

Zanjan

**Postal code**

**Phone**

+98 24 3302 3270

**Fax**

**Email**

vrashtchi@gmail.com

**Web page address**

## 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*