Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the effects of ketofol (Ketamine-Propofol mixture) with propofol on Transient agitation in children undergoing Adenotonsillectomy

Protocol summary

Study aim
Comparison of the effects of ketofol (Ketamine-Propofol mixture) with propofol on Transient agitation in children undergoing Adenotonsillectomy

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 64 patients. A random number table will be used for randomization.

Settings and conduct
This study is performed in Razi Hospital of Birjand, South Khorasan Province. 64 patients were randomly divided into two groups of adenotonsillectomy receiving propofol and ketofol. Then the agitation of patients in both groups is evaluated by the nurse at 15, 30 minutes in the recovery room and 2, 4 and 6 hours after surgery in the ward. Postoperative complications in patients, including: the presence or absence of nausea, vomiting, as well as the Modified objective pain score will be evaluated.

Participants/Inclusion and exclusion criteria
Candidates for tonsillectomy (adenotonsillectomy) who referred to Razi Hospital in Birjand in 1400. Inclusion criteria include: patients with ASA class one and two, aged 3 to 9 years, without any kinds of addiction and requirement to prescribe any narcotic drugs in recovery phase as well as any known previous propofol allergy reactions. exclusion criteria are defined as having mental and behavioral disorders, a specific rare disease, Cerebral trauma ,intracranial mass or bleeding and any congenital heart diseases.

Intervention groups
Intervention group 1, Patients receiving propofol made by Fresenius Kabi Company, Germany as a general intravenous anesthetic at a dose of 2 mg /kg daily before surgery. Intervention group 2, patients who receive ketofol (40 mg Ketamine made by Rotex Medica, Germany + 160 mg propofol 1%) as an intravenous anesthetic before surgery.

Main outcome variables
Agitation

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190618043934N12**
Registration date: **2021-07-11, 1400/04/20**
Registration timing: **retrospective**

Last update: **2021-07-11, 1400/04/20**
Update count: **0**

Registration date
2021-07-11, 1400/04/20

Registrant information
Name
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-04-04, 1400/01/15
Expected recruitment end date
2021-07-06, 1400/04/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of ketofol (Ketamine-Propofol mixture) with propofol on Transient agitation in children undergoing Adenotonsillectomy

Public title

Effects of propofol and ketofol on transient agitation induced by adenotonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ASA class one and two Age 3 to 9 years Without any addiction Without any requirements to prescribe any Narcotic drugs in recovery phase Without any known previous propofol allergy reactions

Exclusion criteria:

Having mental and behavioral disorders Having a specific illness Cerebral trauma and bleeding or intracerebral mass Having congenital heart disease

Age

From **3 years** old to **9 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will be randomly divided into two groups after intervention with two drugs called ketofol (A) or propofol (B) using the block randomization process. Firstly, various quadruple blocks are created using a sealed envelope (AABB, BBAA, ABAB, BABA, ABBA, and BABA). One of these blocks is selected randomly and according to the order mentioned in the selected block, patients will be divided into one of two groups , namely A or B. Then randomization would be performed for other patients in the similar way.

Blinding (investigator's opinion)

Double blinded

Blinding description

Outcome evaluator=the nurse who was not informed of the type of medication received by the children, performed the necessary evaluation 15 and 30 minutes after the surgery in the recovery room as well as 2,4 and 6 hours post surgery evaluation which were done in the ward. Then, the evaluation data will be submitted to the specific checklist designed for this purpose. The children participating in the study, are not informed of the anesthetic agents that were given to them. Because they are not conscious while going under anesthesia and their lack of information about these kinds of anesthetic agents. The analyst= the analyst does not have any information about the placement of people in the study and conducts analysis on data based on the codes defined by the study leader

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Birjand University of Medical Sciences, Ghaffari Blvd, Birjand Town

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2021-03-01, 1399/12/11

Ethics committee reference number

IR.BUMS.REC.1399.526

Health conditions studied

1

Description of health condition studied

Tonsillitis

ICD-10 code

J03

ICD-10 code description

Acute tonsillitis

Primary outcomes

1

Description

Agitation

Timepoint

15, 30 minutes after being in the recovery room and 2, 4 and 6 hours after surgery in the ward

Method of measurement

Using the Modified objective pain score criterion (MOPS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: The first group in the interventional study are patients who received propofol (made by Fresnius Kabi company in Germany) as a general intravenous anesthetic with the prescribed dose of 2 mg per kg for induction anesthesia as well as 0.5 mg/kg dosage of atracurium ampoule as a skeletal muscle relaxant before the surgery.
Category
Treatment - Drugs

2

Description
Intervention group 2: The second group in the interventional study are patients who are given ketofol in the ratio of 1 : 4 (40 mg ketamine made by Rotex Medica company in Germany + 160 mg propofol 1%) as a preoperative intravenous anesthetic agent for induction anesthesia as well as 0.5 mg/kg dosage of atracurium ampoule as a skeletal muscle relaxant before the surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi Hospital_Birjand
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
Zabihullah Mohaghegh
Position
Student
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available