

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Comparison of Sodium thiopental versus Midazolam-Ketamine in postoperative agitation after pediatric tonsillectomy

Protocol summary

Summary

The goal of the present randomized clinical trial study was to assess and compare effects of Sodium thiopental versus Midazolam-Ketamine on postoperative agitation after pediatric tonsillectomy. Inclusion criteria: children aged between 5 and 15 years candidating tonsillectomy, who were group in class 1 and 2 anesthesia. Exclusion criteria : Inability to intubation, History of use barbiturates. The study was done on children, who had been referred to Valiasr hospital for tonsillectomy Totally, 50 patients between 5 and 15 years were selected based on criteria and were randomly divided into two 25 patient groups (Nesdonal and Midazolam-Ketamine group) In the first group nesdonal 5mg/kg/IV, in the second group ketamine 1mg/kg and midazolam 0.01 mg/kg, were administered intravenous. level of sedation was evaluated by the Ramsay Sedation Scale postoperative

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201205066808N4**
Registration date: **2014-06-26, 1393/04/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-26, 1393/04/05

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Birjand University of Medical Sciences

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Sodium thiopental versus Midazolam-Ketamine in postoperative agitation after pediatric tonsillectomy

Public title

effect of Sodium thiopental versus Midazolam-Ketamine in postoperative agitation after pediatric tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children aged between 5 and 15 years ; class 1 and 2 anesthesia; Candid of surgery tonsillectomy
Exclusion criteria : Inability to intubation; History use of barbiturates

Age

From **5 years** old to **15 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

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

Birjand University of Medical Sciences

Street address

Birjand University of Medical Sciences, Birjand,
Jonoubi Khorasan, Iran

City

Birjand

Postal code

Approval date

2013-04-15, 1392/01/26

Ethics committee reference number

772

Health conditions studied

1

Description of health condition studied

tonsillectomy

ICD-10 code

J35.1

ICD-10 code description

Hypertrophy of tonsils

Primary outcomes

1

Description

Sedation score

Timepoint

postoperative

Method of measurement

Ramsay Sedation Scale

Secondary outcomes

1

Description

Pulse

Timepoint

Before, during and postoperative

Method of measurement

Pulse oximeter

2

Description

Oxygen saturation of arterial blood

Timepoint

Before, during and postoperative

Method of measurement

Pulse oximeter

Intervention groups

1

Description

nesdonal group : nesdonal 5 mg per kg

Category

Treatment - Drugs

2

Description

midazolam- ketamin group:midazolam1mg per kg and
midazolam 0.01 mg per kg intravenous

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Street address

Valiasr Hospital, Birjand University of Medical
Sciences, Birjand, Jonoubi khorasan, Iran

City

Birjand

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

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Street address

Birjand University of Medical Sciences, Ghafarie

street, Birjand, Jonoubi khorasan, Iran

City

Birjand

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

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

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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