

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Comparison of the effect of midazolam-ketamine with ketamine-propofol on post-tonsillectomy agitation in children

Protocol summary

Study aim

Comparison of the effect of midazolam-ketamine with ketamine-propofol on post-tonsillectomy agitation in children

Design

Double-blind randomized clinical trial

Settings and conduct

Intervention 1: The 1st group will receive ketamine 0.5 mg/kg/IV and midazolam 0.01 mg/kg/IV, 10 minute before the end of the surgery. Intervention2: The second group will receive propofol 1 mg/kg/IV and ketamine 0.5 mg/kg, 10 minute before the end of the surgery. Intervention3: The third group received ketamine 0.5 mg/kg/IV, 10 minute before the end of the surgery.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: ASA I-II, Airway class I-II, Normal BMI, children (aged 5-15) scheduled for elective adenotonsillectomy, (ASA Class 1 and 2), isoflurane based anesthesia. Exclusion Criteria: Past history of neuropsychiatric illness, CHD, URTI, seizure, drug reactions. Any past history of post operation complications. Also children with any complication of surgery or anesthesia that could cause agitation itself.

Intervention groups

Intervention 1: The 1st group will receive ketamine 0.5 mg/kg/IV and midazolam 0.01 mg/kg/IV, 10 minute before the end of the surgery. Intervention2: The second group will receive propofol 1 mg/kg/IV and ketamine 0.5 mg/kg, 10 minute before the end of the surgery. Intervention3: The third group received ketamine 0.5 mg/kg/IV, 10 minute before the end of the surgery.

Main outcome variables

Pain,Sedation,PACU duration.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N92**

Registration date: **2020-01-06, 1398/10/16**

Registration timing: **prospective**

Last update: **2020-01-06, 1398/10/16**

Update count: **0**

Registration date

2020-01-06, 1398/10/16

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-04, 1398/11/15

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of midazolam-ketamine with ketamine-propofol on post-tonsillectomy agitation in children

Public title

Comparison of the effect of midazolam-ketamine with ketamine-propofol on post-tonsillectomy agitation in children

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

ASA I-II Airway class I-II Normal BMI children aged 5-15 children candidate for elective adenotonsillectomy Isoflurane based anesthesia

Exclusion criteria:

History of neuropsychiatric illness CHD URTI Seizure Drug reactions Any history of post operation complications Any complication of surgery or anesthesia that could cause agitation itself

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

These children will be randomly divided into 3 groups of 50 cases based on randomization chart which is derived from www.randomization.org.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assistant anesthesiologist who's not involved in the data collection will prepare the syringe for each patient. Anesthesia nurse who is present in the operating room will not provide any information to the recovery staff after the surgery and deliver the patient to the recovery room, while, the patient, nurse, recovery officer, and data analyst will be briefed on the study. Have been

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2018-02-22, 1396/12/03

Ethics committee reference number

IR.SUMS.MED.REC.1396.86

Health conditions studied

1

Description of health condition studied

Tonsillectomy

ICD-10 code

J35.01

ICD-10 code description

Chronic tonsillitis

Primary outcomes

1

Description

Sedation

Timepoint

At arrival to recovery room 5 minute, 10 minute, 20 minute and on recovery room discharge.

Method of measurement

Richmond Agitation & Sedation Scale (RASS)

2

Description

Pain

Timepoint

At arrival to recovery room 5 minute, 10 minute, 20 minute and on recovery room discharge.

Method of measurement

Objective Pain Scale (OPS)

3

Description

Recover duration

Timepoint

At arrival to recovery room 5 minute, 10 minute, 20 minute and on recovery room discharge.

Method of measurement

Modified Aldrete score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The 1st group will receive ketamine 0.5 mg/kg and midazolam 0.01 mg/kg, 10 minute before the end of the surgery.

Category

Prevention

2

Description

Intervention group: The second group will receive propofol 1 mg/kg and ketamine 0.5 mg/kg, 10 minute before the end of the surgery.

Category

Prevention

3

Description

Intervention group: The third group received ketamine 0.5 mg/kg, 10 minute before the end of the surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Khalili Hospital

Full name of responsible person

Rezvan Haghghat

Street address

Khalili Street, Khalili Hospital

City

Shiraz

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Postal code

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Phone

+98 71 3627 1671

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Khalili.hos@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

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sacrc@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Rezvan Haghghat

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Its against our policies.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available