

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Intranasal midazolam alone versus midazolam/ketamine combination for preoperative sedation in pediatric patients undergoing ophthalmic procedures: A randomized controlled trial

Protocol summary

Study aim

Assessing the efficacy and safety of intranasal midazolam alone versus midazolam/ketamine combination for preoperative sedation prior to ophthalmic procedures in preschool children.

Design

Parallel group randomized controlled clinical trial with 1:1 allocation ratio.

Settings and conduct

Research Institute of Ophthalmology, Giza, Egypt.

Participants/Inclusion and exclusion criteria

We will include children (male or female) aged from 3 to 7 years old, ASA I or II. We will exclude children with anticipated difficult airways [such as facial deformity, cervical spine injury, or some syndromes (e.g. Pierre robin syndrome, Apert syndrome, and Teacher Collins syndrome)], increased risk of aspiration [as in anatomical abnormalities, such as cleft palate and problems in the esophagus, neuromuscular diseases, and cerebral palsy], central or obstructive sleep apnea, or previous allergy to the used drugs.

Intervention groups

The first group will be given midazolam intranasally in a dose of 0.5 mg/kg and the second group will be given a combination of intranasal midazolam (0.25 mg/kg) and ketamine (1 mg/kg). The drugs will be administered 15 minutes prior to induction of anesthesia.

Main outcome variables

The primary outcome variables include preoperative level of sedation, postoperative agitation, and easiness of separation. The secondary outcomes include intraoperative oxygen saturation and pulse rate as well as postoperative nausea and vomiting .

General information

Reason for update

Finished recruitment and end of the trial

Acronym

IRCT registration information

IRCT registration number: **IRCT20201220049777N1**

Registration date: **2020-12-31, 1399/10/11**

Registration timing: **prospective**

Last update: **2021-02-18, 1399/11/30**

Update count: **1**

Registration date

2020-12-31, 1399/10/11

Registrant information

Name

Noha Osama

Name of organization / entity

Research Institute of Ophthalmology

Country

Egypt

Phone

+20 2 35735688

Email address

noha.a.osama22@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-15, 1399/10/26

Expected recruitment end date

2021-04-15, 1400/01/26

Actual recruitment start date

2021-01-15, 1399/10/26

Actual recruitment end date

2021-02-08, 1399/11/20

Trial completion date

2021-02-08, 1399/11/20

Scientific title

Intranasal midazolam alone versus midazolam/ketamine combination for preoperative sedation in pediatric patients undergoing ophthalmic procedures: A randomized controlled trial

Public title

Intranasal midazolam/ketamine combination for preoperative sedation in pediatrics

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children (male or female) aged from 3 to 7 years old ASA I or II Children with disability or special needs such as autism and Down syndrome Children who underwent multiple operative procedures Children with history of stormy anesthetic induction or emergence

Exclusion criteria:

Anticipated difficult airways, such as facial deformity, cervical spine injury, or some syndromes (e.g. Pierre robin syndrome, Apert syndrome, and Teacher Collins syndrome). Increased risk of aspiration as in anatomical abnormalities, such as cleft palate and problems in the esophagus, neuromuscular diseases, and cerebral palsy. Central or obstructive sleep apnea. Previous allergy or adverse reaction to the used drugs.

Age

From **3 years** old to **7 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **46**

Actual sample size reached: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

We will use the sequentially numbered, opaque sealed envelopes method. We will use envelopes that are impermeable to intense light, and the allocation sequence will be concealed from the physicians enrolling and assessing participants. To prevent subversion of the allocation sequence, the name and hospital admission number of the participant will be written on the envelope. Carbon paper will transfer the information onto the allocation card inside the envelope. Corresponding envelopes will be opened only after the enrolled participants complete all baseline assessments and it is time to allocate the intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

Only participants will be blinded to the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethical Committee of the Research Institute of Ophthalmology

Street address

2 El Ahram Street

City

Giza

Postal code

12557

Approval date

2020-11-08, 1399/08/18

Ethics committee reference number

8-11-2020

Health conditions studied

1

Description of health condition studied

Preoperative sedation in pediatric patients undergoing ophthalmic procedures.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Preoperative level of sedation

Timepoint

10 minutes after sedation is given

Method of measurement

6-Point Pediatric Sedation State Scale

2

Description

Postoperative agitation

Timepoint

at the time of patient recovery

Method of measurement

Emergence Agitation Scale

3

Description

Easiness of separation

Timepoint

at the time of separation

Method of measurement

Separation and Induction Score

Secondary outcomes

1

Description

Oxygen saturation

Timepoint

every 5 minutes intraoperatively

Method of measurement

pulse oximetry

2

Description

Pulse rate

Timepoint

every 5 minutes intraoperatively

Method of measurement

manually

3

Description

Postoperative nausea and vomiting

Timepoint

30 minutes after recovery

Method of measurement

clinical evaluation

Intervention groups

1

Description

Intervention group 1: The patients will be given midazolam intranasally in a dose of 0.5 mg/kg. The drug will be administered 15 minutes prior to induction of anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group 2: The patients will be given a combination of intranasal midazolam (0.25 mg/kg) and ketamine (1 mg/kg). The drugs will be administered 15 minutes prior to induction of anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Research Institute of Ophthalmology

Full name of responsible person

Dr. Noha Osama

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Self-funded

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Research Institute of Ophthalmology

Full name of responsible person

Noha Osama

Position

Assistant professor

Latest degree

Medical doctor

Other areas of specialty/work

Ophthalmology
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Person responsible for scientific inquiries

Contact

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Research Institute of Ophthalmology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Title and more details about the data/document

Intranasal midazolam and ketamine for preoperative sedation IPD set (all collected deidentified IPD).

When the data will become available and for how long

Beginning 6 months and ending 24 months following article publication

To whom data/document is available

Researchers from academic institutions whose proposal for the use of data has been approved by an independent review committee identified for this purpose.

Under which criteria data/document could be used

For IPD meta-analysis.

From where data/document is obtainable

From the PI.

What processes are involved for a request to access data/document

A proposal for the use of data to be submitted to the PI, then evaluated by an independent review committee identified for this purpose.

Comments