Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Oct 2023

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
Street address
2 El Ahram Street
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Sponsors / Funding sources

1

Sponsor
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Research Institute of Ophthalmology
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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 updating data

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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