Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison efficacy of nebulized Dexmedetomidine-ketamine and midazolam-ketamine in preoperative sedation in pediatric

Protocol summary

Study aim
Efficacy of nebulized Dexmedetomidine-ketamine and midazolam-ketamine in preoperative sedation for pediatric ophthalmic surgery

Design
A clinical trial with a control group, double-blind, randomized, phase 3 on 60 patients was used for randomization using the rand function of Excel software.

Settings and conduct
double-blind, prospective clinical randomized controlled trial study was conducted in Farabi Hospital, Tehran, Iran, on 60 patients. The patients are divided into two groups of 30 people. An independent researcher who is not involved in the study opens the envelopes one hour before the start of anesthesia, and the drugs are prepared in identical syringes with matching random codes. Informed consent will be obtained from parents or authorized guardians. Participants in the intervention group will receive nebulized dexmedetomidine (2 µg/kg) with ketamine (1 mg/kg) and the control group will receive nebulized midazolam (0.1 mg/kg) with ketamine (1 mg/kg). The study drugs are administered through a conventional nebulizer with a mouthpiece with oxygen at a rate of 6 L/min, 30 minutes before surgery.

Participants/Inclusion and exclusion criteria
Inclusion criteria: ASA I and II؛ Children aged 3-7 years؛ Elective eye surgery under general anesthesia Exclusion criteria: Renal or hepatic dysfunction؛ allergy to midazolam؛ asthma؛ neurologic disease

Intervention groups
nebulized Dexmedetomidine-ketamine and midazolam-ketamine

Main outcome variables
Sedation Level؛ Mask Acceptance؛ Parental separation؛ Nausea, vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121205011676N7**
Registration date: **2024-09-23, 1403/07/02**
Registration timing: **retrospective**

Last update: **2024-09-23, 1403/07/02**
Update count: **0**

Registration date
2024-09-23, 1403/07/02

Registrant information

Name
Abbas Ostadalipour

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-08-05, 1403/05/15

Expected recruitment end date
2024-09-20, 1403/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison efficacy of nebulized Dexmedetomidine-ketamine and midazolam-ketamine in preoperative

sedation in pediatric

Public title
Comparison efficacy of nebulized Dexmedetomidine-ketamine and midazolam-ketamine in preoperative sedation
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
ASA I and II Children aged 3-7 years3 Elective eye surgery under general anesthesia
Exclusion criteria:
Hepatic renal failure Neurologic disease Asthma
Age
From **3 years** old to **7 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
To ensure an equal number of participants in each group, a total of 60 people were selected for the study. We used a computer randomization table and the block method for random sequence generation, using EXCEL 2016. Here's how it worked: first, a random sequence was created, and then 60 envelopes were prepared, each containing a card with one of the random sequences. To maintain the randomness, we numbered the envelopes sequentially on the outside and sealed them to prevent any visibility of their contents. The sealed envelopes were then placed in a box. When participants were eligible to enter the study, we opened the envelopes in the order of their entry, revealing the assigned group for each participant.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is randomized double-blind because both the patients, the anesthesiologist responsible for data collection and scoring based on the questionnaires, the leading researcher, and the operating room personnel, including the anesthetist, recovery nurse, operating room expert, and those who prepared the draft of the article. They are kept blind. An independent investigator not involved in the study opens the envelopes one hour before the start of anesthesia, and the drugs are prepared in identical syringes with matching random codes.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Farabi Hospital, Tehran University of Medical Sciences
Street address
Farabi Hospital, South Kargar St., Qazvin Square
City
Tehran
Province
Tehran
Postal code
1336616351
Approval date
2024-05-11, 1403/02/22
Ethics committee reference number
IR.TUMS.FARABIH.REC.1403.013

Health conditions studied

1

Description of health condition studied
efficacy of preoperative sedation for pediatric ophthalmic surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sedation
Timepoint
Minutes fifteen and thirty
Method of measurement
The degree of sedation is evaluated using the RAMSAY sedation scale.1: Patient is anxious, agitated or restless, or both. 2: Patient is oriented, co-operative and tranquil. 3: Patient responds to commands only. 4: Patient exhibits brisk response to light glabellar tap or loud auditory stimulus. 5: Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus. 6: Patient exhibits no response

2

Description
Mask Acceptance
Timepoint

Minutes fifteen and thirty

Method of measurement

The acceptability of the face mask is determined based on the above Corda system: Excellent= Acceptance without any complaint; Good= Compliant, momentarily teary but then agreed to take medication; Fair= Complaint, initially disobedient but eventually agreed to take medication; Poor= Refuse medication

3

Description

Parental separation

Timepoint

Minutes fifteen and thirty

Method of measurement

At 0 and 15 minutes, separation anxiety is assessed using the Point Parental Separation Anxiety Scale (PSAS). 1. Easily detachable; 2. Moaning but confident; 3. She cries and can't be sure, clinging to her parents; 4. He cries and clings to his parents.

4

Description

Determining the prevalence of nausea and vomiting after receiving medication

Timepoint

Minutes 0 and 15 and during postoperative recovery

Method of measurement

Minutes 0 and 15 minutes and during the recovery after the operation will be recorded by the doctor in the relevant form

Secondary outcomes

empty

Intervention groups

1

Description

The patients are divided into two groups: the intervention group includes patients with nebulized midazolam-ketamine. In the midazolam-ketamine nebulized group, it is 0.3 mg per kg of midazolam and 3 mg per kg of ketamine and in 2 cc of normal saline. Patients are allowed to consume clear liquids up to 2 hours before surgery and solid or semi-solid foods up to 8 hours before surgery. Regular monitoring (plus oximetry, non-invasive blood pressure, and EKG) is done in the pre-anesthesia room with a guardian, and children are given nebulizers 15 minutes before the operation. A typical hospital jet nebulizer comes with a mouthpiece that injects 100% oxygen continuously at 10 liters per minute. The nurse guarantees the correct use of the nebulizer and the final administration of the solution. The degree of sedation is evaluated using the RAMSAY sedation scale.

Category

Treatment - Drugs

2

Description

Control group: includes patients who are going to take nebulized dexmedetomidine-ketamine. In the group, dexmedetomidine DK is 2 micrograms per kilogram and ketamine is 3 mg per kilogram in 2 cc of normal saline. Patients are allowed to consume clear liquids up to 2 hours before surgery, as well as solid or semi-solid foods up to 8 hours before surgery. Regular monitoring (plus oximetry, non-invasive blood pressure and EKG) is done in the pre-anesthesia room with the presence of a guardian and children are given nebulizer 15 minutes before the operation. A typical hospital jet nebulizer comes with a mouthpiece that injects 100% oxygen continuously at a rate of 10 liters per minute. The correct use of the nebulizer and the final administration of the solution are guaranteed by the nurse. The degree of sedation is evaluated using the RAMSAY sedation scale.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farabi hospital

Full name of responsible person

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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?
Yes

Title of funding source
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Abbas Ostadalipour

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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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
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Part of the data, such as information related to the main outcome or similar, can be shared.

When the data will become available and for how long

After printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Non-identifiable personal data or other documentation for larger studies

From where data/document is obtainable

Applicants can email the project manager, Dr.Ostadalipour, at a-ostadalipour@tums.ac.ir to receive the desired documents or data.

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

Applicants can email the responsible author at a-ostadalipour@tums.ac.ir to receive the desired documents or data and describe the required study and information.

Comments