

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

Country

Iran (Islamic Republic of)

Phone

+98 21 8833 1595

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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

Abbas Ostadalipour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbari Sari

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Building of Vice chancellor for Research, Tehran University of Medical Sciences and Health Services., Ghods St., Cross, Keshavarz Blvd.,

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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

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Person responsible for scientific inquiries

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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