Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Assessment and Comparison of the effectiveness of nebulized vs. oral midazolam as a sedative premedication in pediatric eye surgery patients

Protocol summary

Study aim

Assessing and comparing the effectiveness of nebulized vs. oral midazolam as a sedative premedication in pediatric eye surgery patients

Design

A randomized controlled trial single blind study which is single institutional, will be conducted in Farabi Eye hospital, Tehran, Iran. The patients will be divided into two groups where Group N includes the patient with Nebulized midazolam, which will be nebulized 0.5 mg/kg in 5 cc normal saline and Group O will take oral solution which is 0.5 mg/kg (the standard midazolam syrup) and the face mask used for them will not contain any form of drug. Both groups will receive 5 cc dextrose orally.Vital signs will be monitored in the pre-anesthesia room with the guardian present till 30 minutes.

Settings and conduct

In this single institutional single blinded clinical trial, 70 patients aging from 3-7 years who are candidates for eye surgery under general anesthesia will be randomly divided into two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. American Society of Anesthesiologists (ASA) I and II 2. Children aged 3-7 years 3. Eye surgery candidate under general anesthesia Exclusion criteria: 1. Patients with renal or hepatic dysfunction ۲. History of midazolam allergy ۳. History of asthma ۴. Pre-existing neurologic disease

Intervention groups

The patients will be divided into two groups where Group N includes the patient with Nebulized midazolam, who will take the drug as 0.5 mg/kg in 5cc normal saline and will be nebulized through the face mask. In Group O, the oral solution will be given which is 0.5 mg/kg (the standard midazolam syrup) and the face mask used for them will not contain any form of drug. Both groups will receive 5 cc dextrose orally.

Main outcome variables

Sedation level of nebulized vs oral midazolam in pediatric eye surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230117057153N1**
Registration date: **2023-02-01, 1401/11/12**
Registration timing: **prospective**

Last update: **2023-02-01, 1401/11/12**
Update count: **0**

Registration date

2023-02-01, 1401/11/12

Registrant information

Name

Sumaiya Zahra

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-05, 1401/11/16

Expected recruitment end date

2023-02-18, 1401/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessment and Comparison of the effectiveness of nebulized vs. oral midazolam as a sedative premedication in pediatric eye surgery patients

Public title
Comparison of the effect of midazolam in oral and nebulized form

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
ASA I and II Children aged 3 to 7 years Eye surgery under general anesthesia

Exclusion criteria:
Patients with renal or hepatic dysfunction History of midazolam allergy History of asthma Pre-existing neurologic disease

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

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
A randomization list will be generated using a table with the random property in Excel. After that, the information will be sent in numbered sealed envelopes.

Blinding (investigator's opinion)
Single blinded

Blinding description
The person assessing the outcomes of the information will be unaware of the drug given to each patients.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics comittee of Tehran University of Medical Sciences

Street address
13th Floor, Block- A, Central Headquarters of the Ministry of Health and Medical Education, Iran Sima Street, Quds Town (West), between South Flamek and Zarafshan, Quds Town (West), Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1336616351

Approval date
2023-01-12, 1401/10/22

Ethics committee reference number
IR.TUMS.FARABIH.REC.1401.046

Health conditions studied

1

Description of health condition studied
This study is conducted for sedation in children undergoing eye surgeries. The entry criteria of our children should not have any underlying disease and be between 3 and 7 years old.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Determining sedation level using RAMSAY score within 30 minutes after administration of nebulized vs oral midazolam in pediatric eye surgery patients.

Timepoint
30 minutes after drug administration

Method of measurement
RAMSAY sedation score (0-6)

Secondary outcomes

1

Description
Time taken to reach RSS 4 (RSS= Ramsay Sedation Score)

Timepoint
Within 30 minutes whenever it reaches RSS 4

Method of measurement
Time Unit

2

Description
Facemask acceptance during drug delivery

Timepoint
During the sedation procedure

Method of measurement
Four point Mask Acceptance Scale 1.Excellent: Unafraid, cooperative, and accepts mask easily. 2, Good: Slight fear of mask, easily reassurediii. 3. Fair: Moderate fear of mask, not calmed with reassuranceiv. 4. Poor: Terrified,

crying and combative

3

Description
Ease of separation from parents
Timepoint
At the end of drug delivery (after 30 minute)
Method of measurement
Parental Separation Anxiety Scale (PSAS) Excellent = Patient unafraid, cooperative, or asleep Good= Slightly afraid/crying, quiet with reassurance Fair= Moderately afraid and crying, not quiet with reassurance Poor= Crying, need for restraint

4

Description
Changes in oxygen saturation
Timepoint
Baseline (at 0 minute after nebulization), 15th miinute and at 30th minute
Method of measurement
Oxygen saturation by pulse oximetry

5

Description
Changes in heart rate
Timepoint
At 0 minute after nebulization, 15th minute and 30th minute
Method of measurement
Heart rate in beat/minute

6

Description
Changes in blood pressure
Timepoint
At 0 minute after nebulization, 15th minute and 30th minute
Method of measurement
Blood pressure in mmHg

Intervention groups

1

Description
Intervention group: The patients will receive the nebulized midazolam will be 0.5 mg/kg in 5 cc normal saline and will be nebulized through the face mask.
Category
Other

2

Description
Patients will recieve oral solution which is 0.5 mg/kg (the standard midazolam syrup) and the face mask used for them will not contain any form of drug.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Farabi Eye Hospital
Full name of responsible person
Abbas Ostadalipour
Street address
Qazvin Square, South Kargar, Tehran, Iran
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Tehran
Postal code
1336616351
Phone
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Abbas Ostadalipour
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Pour Sina Street, District 6, Tehran Province, Tehran, Iran
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1416634793
Phone
+98 21 8889 6696
Email
icedu@tums.ac.ir
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
Sumaiya Zahra
Position
Student
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available