

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 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)

Phone

+98 21 8889 6692

Email address

sumaiyazahra25998@yahoo.com

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 committee 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

Other

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 minute 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 receive 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

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

City

Tehran

Province

Tehran

Postal code

1336616351

Phone

+98 902 072 3064

Email

farabi-ipd@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abbas Ostadalipour

Street address

Pour Sina Street, District 6, Tehran Province, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

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

Fax**Email**

sumaiyazahra25998@yahoo.com

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

A Level or less

Other areas of specialty/work

Medical Student

Street address

Dormitory Kuye Daneshgar, Amirabad, North Kargar St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1439957181

Phone

+98 21 8800 2651

Email

sumaiyazahra110@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Sumaiya Zahra

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical student

Street address

Kuye Daneshgah, North Karegar, Amirabad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1439957181

Phone

+98 21 8889 6692

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Sumaiya Zahra

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical student

Street address

Kuye Daneshgah, North Karegar, Amirabad, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1439957181

Phone

+98 21 8889 6692

Fax**Email**

sumaiyazahra25998@yahoo.com

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