

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing of the effects of intranasal administration of midazolam and dexmedetomidine premeditations in reducing anxiety and sedation of children candidates for inguinal hernia surgery

Protocol summary

Study aim

Comparing the efficacy of intranasal dexmedetomidine and midazolam as premedication for managing preoperative anxiety in children undergoing elective inguinal herniorrhaphy. Identify the optimal premedication to minimize anxiety and facilitate surgical preparation in pediatric patients.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 trial on 70 patients. Blocking method will be used for randomization.

Settings and conduct

The aim of this randomized controlled trial is to compare the sedative and anxiolytic effects of intranasal dexmedetomidine versus midazolam in children aged 2-10 years (ASA physical status I or II) undergoing elective inguinal hernia surgery at Akbar Pediatric Hospital, Mashhad. Children in the intervention group will receive intranasal dexmedetomidine 1 mcg/kg, while those in the control group will receive intranasal midazolam 0.2 mg/kg, 30 minutes prior to induction of anesthesia. Both patients and researchers will be blinded to group allocation. Sedation and anxiety scores will be recorded every 5 minutes from the start of drug administration until 30 minutes post-administration, after which the child will be transferred to the operating room (OR)."

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Children aged 2-10 years, with ASA physical status I or II, scheduled for elective inguinal hernia surgery. Exclusion Criteria: Children who refuse to participate, have allergies to study medications, any psychiatric disorders, upper respiratory tract infections, nasal pathologies causing nasal obstruction, neurological disorders, or a heart rate less than 80 beats per minute at baseline.

Intervention groups

Intervention group : Intranasal dexmedetomidine 1 microgram per kilogram Control group: Intranasal Midazolam 0.2 milligram per kilogram

Main outcome variables

Anxiety Score; Sedation Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240713062419N1**

Registration date: **2024-11-28, 1403/09/08**

Registration timing: **registered_while_recruiting**

Last update: **2024-11-28, 1403/09/08**

Update count: **0**

Registration date

2024-11-28, 1403/09/08

Registrant information

Name

Alireza Bayat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3621 2800

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bayata1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-22, 1403/07/01

Expected recruitment end date

2025-01-20, 1403/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing of the effects of intranasal administration of midazolam and dexmedetomidine premeditations in reducing anxiety and sedation of children candidates for inguinal hernia surgery

Public title
Comparing the effects of intranasal administration of midazolam and dexmedetomidine As premedication in reducing anxiety and sedation in children

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Children aged 2 to 10 Candidate for Inguinal Hernia surgery American Society of Anesthesiologists (ASA) Classification of Patient's I and II class
Exclusion criteria:
Dissatisfaction Allergy to drugs used for study Nasal Pathologies (like tumors, polyps, epistaxis,...) Upper respiratory tract infections Any mental disorder Any Neurologic disorder Heart Rate below 80

Age
From **2 years** old to **10 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Block randomization was employed to allocate participants randomly. Block sizes of 4, 6, and 8 were selected for this study. A total of 12 blocks were created, comprising 4 blocks of size 4, 5 blocks of size 6, and 3 blocks of size 8. Each block contained a random sequence of participants assigned to either study arm. These blocks were sealed in opaque envelopes and randomized. For each eligible participant, a block was randomly selected, and the participant was assigned to the corresponding study arm based on the sequence within that block. This process continued until all blocks were exhausted and all participants were allocated.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participant: Parents provided informed consent for their child to be randomly assigned to either the intervention

or control group. Researcher: The researcher was blinded to group allocation until after randomization to minimize bias. Assessor: The assessor was blinded to treatment allocation

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Imam Reza Hospital Educational, Research and Treatment Center- Mashhad
Street address
Danesh va salamat town - Fakkoori blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191

Approval date
2024-07-01, 1403/04/11

Ethics committee reference number
IR.MUMS.IRH.REC.1403.098

Health conditions studied

1

Description of health condition studied
Hernia Surgery
ICD-10 code
K40.9
ICD-10 code description
Unilateral inguinal hernia, without obstruction or gangrene

2

Description of health condition studied
Inguinal Hernia
ICD-10 code
K40.2
ICD-10 code description
Bilateral inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description

Anxiety Score
Timepoint
At the time of drug administration and then every 5 minutes until 30 minutes
Method of measurement
Anxiety Score based on Akin et al Anxiety Score

2

Description
Sedation Score
Timepoint
At the time of drug administration and then every 5 minutes until 30 minutes
Method of measurement
Sedation Score by using Modified Observers Assessment of Alertness/Sedation Scale (MOAA/S)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intranasal dexmedetomidine 1 microgram per kilogram
Category
Treatment - Drugs

2

Description
Control group: Intranasal Midazolam 0.2 milligram per kilogram
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Pediatric Hospital
Full name of responsible person
Alireza Sabzevari
Street address
No 14, Shahid Kaveh Blv
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Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Qurashi Building, Research and Technology Vice-Chancellor , Danshgah Ave. , Mashhad , Iran
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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Alireza Sabzevari
Position
Associated professor
Latest degree
Subspecialist
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)

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