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 scientific inquiries

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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