Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effects of Dexmedetomidine and Midazolam on Postoperative Pain and Agitation in Pediatric Patients Undergoing Abdominal Mass Surgery

Protocol summary

Study aim
Comparison of the Effects of Dexmedetomidine and Midazolam on Postoperative Pain and Agitation in Pediatric Patients Undergoing Abdominal Mass Surgery.

Design
A randomized, double-blind, parallel-group clinical trial with 30 participants per group. Randomization was performed using a random number table.

Settings and conduct
Children who are candidates for elective abdominal mass surgery and who refer to Mofid Children's Hospital in Tehran during the study will, if eligible, enter the study and will be randomly allocated to two groups. The drugs are administered by the responsible nurse, in equal volumes and without identifying labels. This study is conducted in a double-blind manner, such that the patients, the treating physician, and the outcome assessor are unaware of the type of intervention.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Children older than 9 months and candidates for elective surgery of abdominal masses, physical status I or II according to ASA (American Society of Anesthesiologists), both sexes, and with parental informed consent. Exclusion criteria: Hypersensitivity to dexmedetomidine or midazolam, significant cardiac, respiratory, hepatic or renal disease, and use of sedative or analgesic medication within 24 hours before surgery.

Intervention groups
Standard induction of anesthesia is performed for all patients and before extubation: dexmedetomidine group (Exir company): 4 micrograms per kilogram dexmedetomidine diluted with 5% dextrose to a volume of 5 milliliters, and midazolam group (Exir company): 0.5 milligrams per kilogram midazolam diluted with the same volume of dextrose. The solution is given to the nurse without a label and administered intranasally to the patient.

Main outcome variables
Emergence agitation;Postoperative pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20250420065398N1**
Registration date: **2026-05-07, 1405/02/17**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-07, 1405/02/17**
Update count: **0**

Registration date
2026-05-07, 1405/02/17

Registrant information
Name
seyed Mehdi Saadatmand
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2024-12-21, 1403/10/01
Expected recruitment end date
2026-06-20, 1405/03/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effects of Dexmedetomidine and Midazolam on Postoperative Pain and Agitation in Pediatric Patients Undergoing Abdominal Mass Surgery

Public title

Comparison of Dexmedetomidine and Midazolam in Children Undergoing Abdominal Mass Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children aged more than 9 months Candidates for elective abdominal mass surgery American Society of Anesthesiologists physical status I or II Both male and female patients Written informed consent obtained from parents or legal guardians

Exclusion criteria:

Known allergy or hypersensitivity to dexmedetomidine or midazolam Presence of significant cardiac, respiratory, hepatic, or renal disease Use of sedative or analgesic drugs within 24 hours before surgery

Age

From **9 months** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Eligible patients will be randomly assigned to one of the two groups receiving dexmedetomidine or midazolam. Randomization will be performed using a simple randomization method and by means of a computer-based random number table. The random allocation sequence will be performed using SPSS software. Group allocation will be concealed by sealed, opaque, and sequentially serial-numbered envelopes that have been prepared by an individual independent of the study implementation team.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a double-blind clinical trial.The study drugs will be prepared in equal volumes and administered intranasally by a nurse who is not involved in the evaluation of patients and data collection.The patients, their parents, clinical caregivers, and outcome assessors will be unaware of the group assignments throughout the study period.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of the School of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Sixth Floor, Number Two University Headquarters Building, Shahid Beheshti University of Medical Sciences and Health Services, Arabi Street, Yemen Street, Shahid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2025-12-16, 1404/09/25

Ethics committee reference number

IR.SBMU.MSP.REC.1404.625

Health conditions studied

1

Description of health condition studied

Pediatric patients undergoing abdominal mass surgery

ICD-10 code

R45.1

ICD-10 code description

Restlessness and agitation

Primary outcomes

1

Description

Emergence agitation severity

Timepoint

At recovery room arrival and during the first 30 minutes after extubation

Method of measurement

Assessed using the Emergence Agitation Scale

Secondary outcomes

1

Description
Postoperative pain intensity
Timepoint
During the first 30 minutes after extubation
Method of measurement
Assessed using the Visual Analog Scale

Intervention groups

1

Description
Intervention group: Patients in this group, after induction of standard general anesthesia including the use of sevoflurane (MAC=8%) and nitrous oxide (60%), and after achieving adequate depth of anesthesia and placement of a venous line and intravenous injection of fentanyl 2 micrograms per kilogram and atracurium 0.5 milligrams per kilogram, and appropriate airway placement. Maintenance of anesthesia is performed using propofol. Before extubation, 4 µg/kg dexmedetomidine from the Exir pharmaceutical company is brought to a volume of 5 milliliters using 5% dextrose solution and, without specifying the composition of the solution, is handed over to the relevant nurse and administered intranasally to the patient.
Category
Treatment - Drugs

2

Description
Control group: Patients in this group, after induction of general anesthesia similar to the intervention group, midazolam 0.5 milligrams per kilogram from the Exir pharmaceutical company is brought to the same volume using dextrose solution and, without specifying the composition of the solution, is handed over to the relevant nurse and administered intranasally to the patient.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Children Hospital
Full name of responsible person
Seyed Mehdi Saadatmand
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Mehdi Saadatmand
Position
Anesthesiology Resident
Latest degree
Medical doctor
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
Yes - There is 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

Title and more details about the data/document
De-identified individual participant data collected during the study

When the data will become available and for how long
Not determined

To whom data/document is available
Access, if any, will be limited to the research team and subject to institutional approval

Under which criteria data/document could be used
Data may be used for academic and research purposes only, subject to ethical approval and data protection regulations

From where data/document is obtainable
Requests should be directed to the principal investigator

What processes are involved for a request to access data/document
Requests will be reviewed by the research team and evaluated based on ethical and institutional policies

Comments