

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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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+98 71 3730 9419

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Recruitment status

Recruitment complete

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

Street address

Mofid Children Hospital, Shariati Street, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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

Anesthesiology

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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