

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation and Comparison of the Effect of Intranasal Dexmedetomidine and Midazolam on Child's Sedation and Cooperation During IV Cannulation Prior to Dental Anesthesia and Heart Rate Changes During Laryngoscopy: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

Evaluation and Comparison of the Effect of Intranasal Dexmedetomidine and Midazolam on Child's Sedation and Cooperation During IV Cannulation Prior to Dental Anesthesia and Heart Rate Changes During Laryngoscopy

Design

This is a randomized clinical trial with parallel design. The study will be conducted on 60 eligible children. Block randomization will be used for randomization, and participants will be allocated into two intervention groups.

Settings and conduct

This non-blinded study will be conducted at the Roozbeh Surgical Center in Isfahan. Before the study begins, the patient's heart rate will be recorded. Furthermore, child anxiety will be assessed using five behavioral indicators: physical activity, speech, facial expression, interaction with the environment, and parental dependence.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Informed Consent; Healthy children 3–5 years of age; Need for general anesthesia for dental treatments. Exclusion criteria: Having contraindications for general anesthesia and nasotracheal intubation on the day of procedure/surgery. History of hypersensitivity to midazolam or dexmedetomidine.

Intervention groups

The first intervention group will receive intranasal dexmedetomidine (Exir Company, Iran) at a dose of 1.5 µg/kg body weight, administered 20 minutes before the induction of anesthesia. The second intervention group will receive intranasal midazolam (Exir Company, Iran) at a dose of 0.2 mg/kg body weight, administered 20 minutes before the induction of anesthesia.

Main outcome variables

Heartbeat; Sedation during venipuncture; Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100621004224N39**

Registration date: **2026-05-12, 1405/02/22**

Registration timing: **prospective**

Last update: **2026-05-12, 1405/02/22**

Update count: **0**

Registration date

2026-05-12, 1405/02/22

Registrant information

Name

Nasser Kaviani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2858

Email address

kaviani@dnt.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-05-20, 1405/02/30

Expected recruitment end date

2026-07-06, 1405/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	
Scientific title	Evaluation and Comparison of the Effect of Intranasal Dexmedetomidine and Midazolam on Child's Sedation and Cooperation During IV Cannulation Prior to Dental Anesthesia and Heart Rate Changes During Laryngoscopy: A Randomized Controlled Clinical Trial
Public title	Comparison of the Effect of Intranasal Dexmedetomidine and Midazolam on Child's Sedation and Cooperation
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Informed Consent Healthy children 3-5 years of age Need for general anesthesia for dental treatments
Exclusion criteria:	Having contraindications for general anesthesia and nasotracheal intubation on the day of procedure/surgery History of hypersensitivity to midazolam or dexmedetomidine Use of sedative or anxiolytic medications within 24 hours prior to the study Severe obesity or severe underweight
Age	From 3 years old to 5 years old
Gender	Both
Phase	N/A
Groups that have been masked	No information
Sample size	Target sample size: 60
Randomization (investigator's opinion)	Randomized
Randomization description	Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site https://www.sealedenvelope.com is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	

Secondary Ids	empty
Ethics committees	
1	
Ethics committee	
Name of ethics committee	Isfahan University of Medical Sciences, Ethics Committee of the Faculty of Medicine
Street address	Isfahan University of Medical Sciences, Hezar Jarib St..
City	Isfahan
Province	Isfahan
Postal code	8174673461
Approval date	2026-04-27, 1405/02/07
Ethics committee reference number	IR.MUI.MED.REC.1405.042
Health conditions studied	
1	
Description of health condition studied	Anxiety
ICD-10 code	F06.4
ICD-10 code description	Anxiety disorder due to known physiological condition
Primary outcomes	
1	
Description	Anxiety
Timepoint	The beginning of the study and the end of the study
Method of measurement	Base on Modified Yale Preoperative Anxiety Scale
2	
Description	Sedation during venipuncture
Timepoint	20 minutes after drug administration, at the same time as venipuncture
Method of measurement	Base on University of Michigan Sedation Scale
3	
Description	Heartbeat
Timepoint	

Before and after laryngoscopy

Method of measurement

Using monitoring

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive intranasal dexmedetomidine (Exir Company, Iran) at a dose of 1.5 µg/kg body weight, administered 20 minutes before the induction of anesthesia.

Category

Treatment - Drugs

2

Description

The second intervention group will receive intranasal midazolam (Exir Company, Iran) at a dose of 0.2 mg/kg body weight, administered 20 minutes before the induction of anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rouzbeh Surgery Center

Full name of responsible person

Nastaran Kaviani

Street address

Arbab St, Sheikh Sadouqi Crossroads

City

Isfahan

Province

Isfahan

Postal code

816581531

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+98 31 3664 3012

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n.kavizni@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Mozhgan Mortazavi

Street address

Isfahan University of Medical Sciences, Hezar Jarib St..

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Province

Isfahan

Postal code

8174673461

Phone

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Email

m.Mortazavi@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Nastaran Kaviani

Position

Dental student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Naser Kavizni

Position

University faculty member

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Dr. Naser Kaviani

Position

University faculty member

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available