Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
recruiting
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
Isfehan

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

Isfehan

Postal code

816581531

Phone

+98 31 3664 3012

Email

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..

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 3071

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

Street address

Isfahan University of Medical Sciences, Faculty of Medicine, Hezar Jarib St..

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3792 3071

Email

n.kaviani@yahoo.com

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
Isfahan University of Medical Sciences, Faculty of Medicine, Hezar Jarib St..

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3071

Email
n.kaviani@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Naser Kaviani

Position
University faculty member

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Isfahan University of Medical Sciences, Faculty of Medicine, Hezar Jarib St..

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3792 3071

Email
n.kaviani@gmail.com

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