

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of oral and intranasal midazolam premedication on sedation before undergoing MRI in children

Protocol summary

Study aim

Comparison of the efficacy of oral and intranasal midazolam premedication on sedation before undergoing MRI in children

Design

This study will be conducted as a randomized, controlled, double-blind (outcome evaluator and statistical analyzer), 3-arm phase 3 clinical trial with parallel groups, on 90 eligible patients. The table of random numbers provided by graphpad.com will be used for randomization.

Settings and conduct

This clinical trial will be conducted on eligible patients admitting to pediatric medical center, Tehran. Pre-sedation will be administered in the preparation room and anesthesia will be performed in the MRI room; Patients will randomly divided into one of 3 control , oral Midazolam and intranasal midazolam groups, and after receiving the intervention, the intended outcomes will be evaluated. In this study, the outcome evaluator and the statistical analyst are unaware of the type of groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA class 1 to 2 according to the American Society of Anesthesiologists; Age is between 6 months to 6 years; The patient is a candidate for MRI under anesthesia; Exclusion criteria: The patient has upper gastrointestinal tract problems, or an active infection, or a structural disorders of the upper respiratory system, or patient is cyanotic, or Having a history of drug allergy, or Severe crying and restlessness of the child immediately before participation;.

Intervention groups

Group 1: 0.5 mg/kg syrup Midazolam PO, 20 minutes prior parental separation to conducting anesthesia Group 2: 0.2 mg/kg nasal spray Midazolam intranasal, 20 minutes prior parental separation to conducting anesthesia Group 3 (Control group): routine anesthesia, without pre-sedation Routine anesthesia: induction with inhaled sevoflurane and 1ml/kg intravenous Propofol

Main outcome variables

Sedation scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151221025641N8**

Registration date: **2024-05-26, 1403/03/06**

Registration timing: **prospective**

Last update: **2024-05-26, 1403/03/06**

Update count: **0**

Registration date

2024-05-26, 1403/03/06

Registrant information

Name

Parisa Kianpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2660 2854

Email address

pk.pioneer1@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-06-04, 1403/03/15

Expected recruitment end date

2024-09-05, 1403/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of oral and intranasal midazolam premedication on sedation before undergoing MRI in children

Public title

Comparison of the efficacy of oral and intranasal midazolam premedication on sedation before undergoing MRI in children

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient is classified as ASA class 1 to 2 according to the American Society of Anesthesiologists; The patient's age is between 6 months to 6 years; The patient is a candidate for MRI under anesthesia;

Exclusion criteria:

The patient has upper gastrointestinal tract problems; The patient has an active infection; The patient has structural disorders of the upper respiratory system; The patient is cyanotic; Having a history of drug allergy to benzodiazepines; Severe crying and restlessness of the child immediately before administering the medicine;

Age

From **6 months** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by random number table method through blocks of 3 created by referring to www.sealedenvelope.com. In this method, 90 eligible patients will be randomly divided into 30 blocks including 3 patients; Then, each of the 3 patients in the block will be randomly assigned to one of the 3 study groups based on the sequence provided by the website, so that 30 patients will be assigned to each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the outcome assessor and the statistical analyst will be unaware of the type of intervention. A trained staff member (anesthetist) who is not a member of the research group, according to the randomization sequence, will enter the patients in the respective groups and prescribes the intervention.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

Street address

Central building, Ghods St., Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1913914435

Approval date

2024-01-07, 1402/10/17

Ethics committee reference number

IR.TUMS.CHMC.REC.1402.165

Health conditions studied**1****Description of health condition studied**

Preanesthetic sedation

ICD-10 code

F13

ICD-10 code description

Sedative, hypnotic, or anxiolytic related disorders

Primary outcomes**1****Description**

Sedation scale

Timepoint

0, 5, 10, 15 and 20 minutes after receiving the intervention

Method of measurement

Scoring system and clinical assessment

Secondary outcomes**1****Description**

Parental separation anxiety scale

Timepoint

20 minutes after receiving the intervention

Method of measurement

Scoring system and clinical assessment

2

Description

Mask acceptance score

Timepoint

20 minutes after receiving the intervention

Method of measurement

Scoring system and clinical assessment

3

Description

Recovery score

Timepoint

Recovery time

Method of measurement

Scoring system and clinical assessment

4

Description

Agitation score

Timepoint

At discharge

Method of measurement

Scoring system and clinical assessment

Intervention groups

1

Description

Intervention group: 0.5 mg/kg syrup Midazolam PO, 20 minutes prior parental separation to conducting anesthesia

Category

Treatment - Drugs

2

Description

Intervention group: 0.2 mg/kg nasal spray Midazolam intranasal, 20 minutes prior parental separation to conducting anesthesia

Category

Treatment - Drugs

3

Description

Control group: routine anesthesia, without pre-sedation

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Children' Medical Center

Full name of responsible person

Ashkan Taghizadeh

Street address

Children's Medical Center, Dr. Mohammad Gharib St.,Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 9000

Email

ataghizadeh@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ali Akbari Sari

Street address

Central building, Ghods Ave., Keshavarz Blvd.

City

Terhan

Province

Tehran

Postal code

1913914435

Phone

+98 21 8163 1000

Email

vcr@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Ashkan Taghizadeh

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Children's Medical Center, Dr. Mohammad Gharib
St.,Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 9000

Email

cmcpr@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ashkan Taghizadeh

Position

Assistant professor

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Phone

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ataghizadeh@sina.tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ashkan Taghizadeh

Position

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+98 21 6147 9000

Email

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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