Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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+98 21 2660 2854
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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.
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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.
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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
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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Person responsible for scientific inquiries

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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

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