Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison study of midazolam and promethazine premedication in MRI outpatients undergone general anesthesia in children, imaging ward of children's medical center 2020

Protocol summary

Study aim

Determining and comparing the effect of oral pretreatment of promethazine and midazolam on sedation of outpatients under MRI with anesthesia in children referred to imaging ward

Design

Clinical trial with control group, with parallel groups, double blind, randomized, on 116 patients, two groups of 58 people. The randomization method of this study will be block randomization. Thus, using random generators, 4 blocks consisting of promethazine and midazolam groups will be formed. The process of assigning patients to the two study groups will be performed by a trained nurse (outside the research team).

Settings and conduct

The study population is children referred to the medical center hospital and the sample of children referred to the clinic is the MRI ward of the Children's medical center hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria will be all patients aged 1 to 10 years old and ASA class 1 and 2. Exclusion criteria: dissatisfaction of parents to participate in the project; genetic and congenital diseases; history of allergy to the studied drugs; behavioral disorders; use of psychiatric drugs and any mental disorders in the child; use sleeping pills before visiting; patients with ASA grade 3 and above; non-Persian speaking family.

Intervention groups

The first group will be given 0.3 mg / kg midazolam (with 20 cc of sugar water) half an hour before separation and the second group will be given 1 mg / kg of promethazine (with 20 cc of sugar water).Their vital signs will then be recorded (including heart rate, blood pressure, respiratory rate).

Main outcome variables

Duration of stay in recovery; sedation score according to Ramsay; maximum PAED as the orthogonal delirium score; satisfaction of recovery nurses with RN satisfaction Score; existence of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200521047530N2**
Registration date: **2020-09-29, 1399/07/08**
Registration timing: **prospective**

Last update: **2020-09-29, 1399/07/08**
Update count: **0**

Registration date

2020-09-29, 1399/07/08

Registrant information

Name

Nima Nazari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6147 2569

Email address

n-nazari@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison study of midazolam and promethazine premedication in MRI outpatients undergone general anesthesia in children, imaging ward of children's medical center 2020

Public title
The comparison study of midazolam and promethazine premedication in MRI outpatients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients aged 1 to 10 years old ASA class 1 and 2 Patients who have referred to the Pediatric Medical Center Hospital for outpatient MRI under anesthesia.
Exclusion criteria:
Dissatisfaction of parents to participate in the project Genetic and congenital diseases History of allergy to the studied drugs behavioral disorders Use of psychiatric drugs and any mental disorders in the child Use sleeping pills before visiting Patients with ASA grade 3 and above Non-Persian speaking family
Age
From **1 year** old to **10 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **116**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method of this study will be block randomization. Thus, using random generators, 4 blocks consisting of promethazine and midazolam groups will be formed. The process of assigning patients to the two study groups will be performed by a trained nurse (outside the research team) and the researchers in this study will not be aware of the allocation process(allocation concealment).
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient himself is unaware of which category he falls into And what kind of anesthetic is given to him. The researcher is also unaware of what kind of medicine is given to each patient. The process of assigning patients to the two study groups will be performed by a trained nurse (outside the research team) and the researchers in this study will not be aware of the allocation process.The data will be collected by a researcher who is unaware of the classification of patients.
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
Keshvarz Blvd- Qods St- Central building of Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
1417653911
Approval date
2020-07-11, 1399/04/21
Ethics committee reference number
IR.TUMS.CHMC.REC.1399.088

Health conditions studied

1

Description of health condition studied
patients candidate for MRI
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Sedation criteria
Timepoint
Measure immediately after entering recovery
Method of measurement
RAMSAY criteria score

2

Description
Delirium emergence score
Timepoint
Measure immediately after entering recovery
Method of measurement
PAED score

Secondary outcomes

1

Description
Recovery time
Timepoint
After entering the recovery
Method of measurement
Interval from admission to recovery ward until discharge

2

Description
Sedation score
Timepoint
After entering the recovery
Method of measurement
Ramsay Score

3

Description
delirium emergence score
Timepoint
After entering the recovery
Method of measurement
PAED score

4

Description
Nurses' satisfaction
Timepoint
After entering the recovery
Method of measurement
RN satisfaction score

5

Description
Nausea and vomiting
Timepoint
After entering the recovery
Method of measurement
View

6

Description
Bronchospasm and laryngospasm
Timepoint
After entering the recovery
Method of measurement
Observation of symptoms and auscultation

Intervention groups

1

Description
Intervention group: Promethazine/ Half an hour before separation, 1 mg / kg promethazine (with 20 cc of sugar water) will be given.
Category
Treatment - Drugs

2

Description
Control group: midazolam/ Half an hour before separation, 0.3 mg / kg midazolam (with 20 cc of sugar water) will be given.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Children's medical center Hospital
Full name of responsible person
Nima Nazari
Street address
Keshavarz Blvd- Gharib St- Children's medical center Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahraian
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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
Nima Nazari
Position
Assistant professor of anesthesiology department
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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

The data will be published in general and in the form of a general report. No personal information or names of study participants will be disclosed.

When the data will become available and for how long

The results will be available from 1400 and after the results are published.

To whom data/document is available

Access will be available to everyone.

Under which criteria data/document could be used

Access will be available to everyone. It will be possible for all people to use the results and data.

From where data/document is obtainable

email:nima.nazari1366@gmail.com Dr. Nima Nazari/ Assistant Professor if Anesthesiology- Tehran University of medical sciences

What processes are involved for a request to access data/document

The request for data submission will be sent to the mentioned email.The data will then be available to everyone.

Comments