Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of oral Promethazine's effect with Midazolam and with Placebo on preoperative anxiety in children (3-8 years old)

Protocol summary

Summary

(1) Aim: Determination and comparison of oral Promethazine's effect, oral Midazolam and Placebo on preoperative anxiety, pulse rate, blood pressure, respiratory rate, nausea and vomiting in referred children (3-8 years old) to Khorramabad Shohadaye Ashayer Hospital. (2) Design: Randomized / Double blind / Controlled with Placebo / Single center. (3) Setting and conduct: Sampling method is based on inclusion criteria. Children are categorized into one of the three groups (Promethazine, Midazolam and Placebo) based on simple randomized allocation. Then interventions are done on them and results are recorded in questionnaire. (4) Participants, Inclusion and exclusion criteria: Sample volume is 123. Inclusion criteria: Children with 3-8 years old / With American Society of Anaesthesiologists (ASA) grade 1 and 2 / under general anaesthesia / elective surgery / lack of chronic disease, prematurity, growth retardation, brain disorders, vision and acoustic disorders / with a written consent form from parents. Exclusion criteria: History of allergy to used drugs in this study / Children with emergency surgery. (5) Interventions: Interventions include three groups (Promethazine, Midazolam and Placebo) and are done 2 hours before surgery. (6) Primary outcome measure: Preoperative anxiety by Yale Preoperative Anxiety Scoring (YPAS)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012073010447N1**
Registration date: **2012-09-24, 1391/07/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-09-24, 1391/07/03

Registrant information

Name
Marzie Sokuti
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Lorestan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Lorestan University of Medical Sciences, Vice chancellor for research

Expected recruitment start date

2012-07-17, 1391/04/27

Expected recruitment end date

2012-09-17, 1391/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral Promethazine's effect with Midazolam and with Placebo on preoperative anxiety in children (3-8 years old)

Public title

Effect of Promethazine and Midazolam on preoperative anxiety

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Children with 3-8 years old / With American Society of Anaesthesiologists (ASA) grade 1 and 2 / under general anaesthesia / elective surgery / lack of chronic disease, prematurity, growth retardation, brain disorders, vision and acoustic disorders / with a written consent form from parents. Exclusion criteria: History of allergy to used drugs in this study / Children with emergency surgery

Age
From **3 years** old to **8 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **123**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
This study is double blind because: (1) Patient does not know that receives which one of three drugs. (2) A nurse of preoperative holding area gives drug to child not researcher. Researcher does not know that patient had received which one of three drugs.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Lorestan University of Medical Sciences

Street address
Pardis (Kamalvand) Academic Centre, Fifth kilometer of Khoramabad-Brujerd road

City
Khoramabad

Postal code

Approval date
2012-07-14, 1391/04/24

Ethics committee reference number
70670/200

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F40, F41,

ICD-10 code description
Neurotic, stress-related and somatoform disorders

Primary outcomes

1

Description
Preoperative anxiety

Timepoint
Before intervention, One hours and 30 minutes after intervention (Separation's time of child from parent) , Two hours after intervention (Before induction of anaesthesia)

Method of measurement
According to Yale Preoperative Anxiety Scoring (YPAS) by questionnaire

Secondary outcomes

1

Description
Age

Timepoint
Before intervention

Method of measurement
According to number of year by questionnaire

2

Description
Sex

Timepoint
Before intervention

Method of measurement
According to phenotype by questionnaire

3

Description
Blood pressure (BP)

Timepoint
Before intervention, Two hours after intervention

Method of measurement
According to millimeter of Mercury by barometer

4

Description
Pulse rate (PR)

Timepoint
Before intervention, Two hours after intervention

Method of measurement
According to number of heartbeat in minute by physical exam

5

Description
Respiratory rate (RR)
Timepoint
Before intervention, Two hours after intervention
Method of measurement
According to number of breathing in minute by physical exam

6

Description
Nausea and vomiting
Timepoint
Before intervention, After surgery
Method of measurement
According to yes or no by questionnaire

Intervention groups

1

Description
Midazolam group: Midazolam syrup (Producted by Midazolam ampule and juice) / Two milligram (mg) in 1 milliliter (ml) / Midazolam Chloridric Acid / With single dose of 0.5 mg per kilogram (kg) up to a maximum of 20 mg / Oral / Once and two hours before surgery / Abureihan Company / Brand name: Versed
Category
Treatment - Drugs

2

Description
Promethazine group: Promethazine syrup / Promethazine Chloridric Acid / With single dose of 0.5 mg per kg up to a maximum of 20 mg / Five mg in 5 ml / Oral / Once and two hours before surgery / Tehran Shimi Company / Brand name: Phenergan
Category
Treatment - Drugs

3

Description
Control group: Oral / Injection water / With single dose of 2-5 ml / Once and 2 hours before surgery / Dana Company / Brand name: Injection water
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Khorramabad Shohadaye Ashayer Hospital
Full name of responsible person
Doctor (Dr) Sedighe Nadri, Anaesthesiologist, Academic
Street address
Shohadaye Ashayer Hospital, Enghelab Street
City
Khorramabad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Lorestan University of Medical Sciences, Vice chancellor for research
Full name of responsible person
Dr. Mohammad Hasan Kayedi
Street address
Pardis (Kamalvand) Academic Centre, Fifth kilometer of Khorramabad - Brujerd road
City
Khorramabad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Lorestan University of Medical Sciences, Vice chancellor for research
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Lorestan University of Medical Sciences
Full name of responsible person
Dr. Sedighe Nadri
Position
Anaesthesiologist, Academic
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty