

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 1320 6359

Email address

nadri.s@lums.ac.ir

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 (Produced 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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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