

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2012-09-24, 1391/07/03

#### 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)

#### 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

#### 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

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**

##### **Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr. Sedighe Nadri

**Position**

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**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*