

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Efficacy of oral promethazine administered pre operatively in relieving anxiety in paediatric patients undergoing surgery under general anaesthesia

#### Protocol summary

##### Study aim

The objective of this research was to assess the effectiveness of oral promethazine in comparison to intranasal midazolam in terms of its sedative and anxiolytic effects prior to anesthesia in children.

##### Design

Single center two arm parallel group randomized control trial of 100 participants with pre operative care and outcome assessment

##### Settings and conduct

This is a non- blinded randomized control trial done at department of anaesthesiology, Combined Military Hospital Rawalpindi, after approval from the ethical board committee

##### Participants/Inclusion and exclusion criteria

Children between ages 2-6 years, of either gender, undergoing elective surgery were included in the present study. Children with respiratory issues, known allergies, and required intravenous anesthesia were excluded from the present study.

##### Intervention groups

Two intervention groups: group M, which received intranasal midazolam at a dosage of 0.3 mg/kg, administered 30 minutes before the start of general anesthesia induction, and group P, which received oral promethazine syrup at a dosage of 1 mg/kg, administered 90 minutes before the start of general anesthesia induction.

##### Main outcome variables

The assessment of the patient's sedation and emotional levels will be conducted using a five-point sedation scale and a four-point emotional scale. The study also includes the examination of heart rate, respiratory rate, and oxygen saturation % to assess the effect of intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230823059228N1**

Registration date: **2023-09-12, 1402/06/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-09-12, 1402/06/21**

Update count: **0**

##### Registration date

2023-09-12, 1402/06/21

##### Registrant information

##### Name

Nasar ul Islam Zakria

##### Name of organization / entity

College of Physicians and Surgeons Pakistan

##### Country

Pakistan

##### Phone

+92 314 4490074

##### Email address

nasarulislam1995@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-05-30, 1402/03/09

##### Expected recruitment end date

2023-11-30, 1402/09/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Efficacy of oral promethazine administered pre operatively in relieving anxiety in paediatric patients undergoing surgery under general anaesthesia

### Public title

Promethazine for relieving anxiety in pre operative children

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Children between ages 2-6 years Both genders Those undergoing elective surgery Those undergoing surgeries under general anaesthesia

#### Exclusion criteria:

Children with respiratory issues Those with known allergies Those requiring intravenous anesthesia

### Age

From **2 years** old to **6 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **100**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block randomization with unit of randomization being the individual participant. Participants will be randomly assigned to either intervention group 1 or intervention group 2, with a 1:1 allocation as per a computer generated randomisation schedule using blocks of random sizes. Allocation concealment not to be carried out

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethical Committee of CMH Rawalpindi

##### Street address

CMH Road, Lalkurti

### City

Rawalpindi

### Postal code

46000

### Approval date

2023-09-04, 1402/06/13

### Ethics committee reference number

444

## Health conditions studied

### 1

#### Description of health condition studied

Pre operative anxiety

#### ICD-10 code

F41.9

#### ICD-10 code description

Anxiety disorder, unspecified

## Primary outcomes

### 1

#### Description

Pre operative anxiety

#### Timepoint

30, 25, 20, 15, 10, and 5 minutes before the scheduled delivery of general anesthesia.

#### Method of measurement

Five-point sedation scale, a four-point emotional scale, heart rate, respiratory rate and oxygen saturation %

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: Children in group M, which received intranasal midazolam at a dosage of 0.3 mg/kg, administered 30 minutes before the start of general anesthesia induction.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group 2 : Children in group P, which received oral promethazine syrup at a dosage of 1 mg/kg, administered 90 minutes before the start of general anesthesia induction.

#### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

**Name of recruitment center**  
Combined Military Hospital, Rawalpindi  
**Full name of responsible person**  
Dr Aqib Ali  
**Street address**  
CMH Road, Lalkurti  
**City**  
Rawalpindi  
**Postal code**  
46000  
**Phone**  
+92 51 9273426  
**Email**  
nasarulislam1995@gmail.com

### Sponsors / Funding sources

## 1

#### Sponsor

**Name of organization / entity**  
Combined Military Hospital Rawalpindi  
**Full name of responsible person**  
Dr Aqib Ali  
**Street address**  
CMH Road, Lalkurti  
**City**  
Rawalpindi  
**Postal code**  
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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**  
Combined Military Hospital Rawalpindi  
**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**  
Combined Military Hospital Rawalpindi  
**Full name of responsible person**

Dr Aqib Ali  
**Position**  
Registrar  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
CMH Road, Lalkurti  
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**Province**  
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### Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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### Person responsible for updating data

#### Contact

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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**

No - There is not 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