Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Phone
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Email
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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
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Latest degree
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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