Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Analgesic Efficacy of Dexmedetomidine and Fentanyl Combined with Ropivacaine for Postoperative Epidural Pain Relief in Pediatric Infra-umbilical Surgeries

Protocol summary

Study aim
To compare efficacy of dexmedetomidine versus fentanyl as adjuvants for 0.2% ropivacaine for postoperative epidural analgesia in children undergoing infra-umbilical surgeries.

Design
A concealed, randomized, double blinded, clinical trial with a parallel group design of 84 Paediatric patients, enrolled between January 2026 and Julyr2026, and followed for 7 months

Settings and conduct
Anesthesia Department, Military Hospital Rawalpindi

Participants/Inclusion and exclusion criteria
Inclusion Criteria : paediatric subjects of both gender age between 2-10 years of age, ASA I, II and undergoing infra-umbilical surgery. Exclusion Criteria : Patients with a history of being sensitive to any of the drugs studied, patients who had contraindications to epidural anaesthesia (local infection, coagulopathy, raised ICP, anatomical deformity of the spine), patients who had a known neurological, cardiovascular, hepatic or renal disorder, and patients who received opioid or sedative drugs within 24 hours prior to surgery were excluded.

Intervention groups
Group D (Dexmedetomidine group) Group F (Fentanyl group)

Main outcome variables
Key outcomes will be time to first analgesic rescue, duration of postoperative analgesia and VAS pain scores at pre-defined time points.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260831070845N2**
Registration date: **2026-11-15, 1405/08/24**
Registration timing: **retrospective**

Last update: **2026-11-15, 1405/08/24**
Update count: **0**

Registration date
2026-11-15, 1405/08/24

Registrant information
Name
Ahsan Ali
Name of organization / entity
Pak Emirates Military Hospital
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Pakistan
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-01-12, 1404/10/22

Expected recruitment end date
2026-07-13, 1405/04/22

Actual recruitment start date
2026-01-01, 1404/10/11

Actual recruitment end date
2026-07-10, 1405/04/19

Trial completion date
2026-07-10, 1405/04/19

Scientific title
Analgesic Efficacy of Dexmedetomidine and Fentanyl Combined with Ropivacaine for Postoperative Epidural Pain Relief in Pediatric Infra-umbilical Surgeries

Public title
"Comparing Pain Relief in Children: The Effects of Dexmedetomidine and Fentanyl with Ropivacaine After Surgery"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
paediatric subjects of both gender age between 2-10 years of age, ASA I, II and undergoing infra-umbilical surgery.
Exclusion criteria:
Patients with a history of being sensitive to any of the drugs studied, patients who had contraindications to epidural anesthesia (local infection, coagulopathy, raised ICP, anatomical deformity of the spine) patients who had a known neurological, cardiovascular, hepatic or renal disorder, patients who received opioid or sedative drugs within 24 hours prior to surgery
Age
From **2 years** old to **10 years** old
Gender
Both

Phase
Bioequivalence
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **84**
Actual sample size reached: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients were divided into two groups by random method. Allocation was done by lottery, and the sequence was not known and was covered by sealed opaque envelopes. The study solutions were being prepared by an independent anesthesiologist, who was not involved in management of the patients. Outcomes were adjudicated in a double-blinded fashion during the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients were divided into two groups by random method. Allocation was done by lottery method, and the sequence was not known and was covered by sealed opaque envelopes. The study solutions were being prepared by an independent anaesthesiologist, who was not involved in management of the patients. Outcomes were adjudicated in a double-blinded fashion during the study.
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical Review Board, PEMH Rawalpindi
Street address
PEMH Rawalpindi
City
Rawalpindi
Postal code
46000
Approval date
2026-07-13, 1405/04/22
Ethics committee reference number
A/28/ERC/72/26

Health conditions studied

1

Description of health condition studied
Post operative Pain
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Visual Analog Score
Timepoint
0,1 and 2 hours after Surgery
Method of measurement
Visual Analog Score

Secondary outcomes

1

Description
Duration of postoperative analgesia
Timepoint
0,6,12 and 24 hours
Method of measurement
VAS

Intervention groups

1

Description

Intervention group:1 (Dexmedetomidine group) received 0.2% ropivacaine 1 mL/kg (maximum 20 mL) with dexmedetomidine 1 mcg/kg epidurally.

Category
Treatment - Drugs

2

Description
Intervention Group 2. (Fentanyl group) received 0.2% ropivacaine 1 mL/kg (maximum 20 mL) epidurally along with fentanyl 2 mcg/kg.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Pak-Emirates Military Hospital Rawa;pindi

Full name of responsible person
Lt Col Dr Ahsan Ali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Pak Emirates Military Hospital Rawalpindi

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

2

Sponsor

Name of organization / entity
Combined Military Hospital Attock

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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 Attock

Proportion provided by this source
100

Public or private sector
Private

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
Pak Emirates Military Hospital Rawalpindi
Full name of responsible person
Lt Col Dr Ahsan Ali
Position
Consultant Anesthetist
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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