Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Nebulized Dexmedetomidine as a Therapeutic Approach for Post-Dural Puncture Headache Following Spinal Anesthesia in Elective Caesarean Delivery

Protocol summary

Study aim
This study aimed to assess how effective nebulized dexmedetomidine is at lowering headache intensity and enhancing satisfaction levels in individuals suffering from post-dural puncture headache.

Design
Randomised, superiority, parallel group trial with blinded outcome assessment. Randomisation was centralised and computerised with concealed randomisation sequence carried out at an external site

Settings and conduct
Both Patient and Caregiver are blinded

Participants/Inclusion and exclusion criteria
Inclusion Criteria All Patients aged between 18 and 40 years, who developed PDPH after spinal anesthesia were included in study Exclusion Criteria Patients with pre-existing chronic headache or migraine disorder, Cardiac Abnormalities including Atrio-Ventricular blocks and Bundle Branch Blocks, uncontrolled hypertension or neurological disease, hypersensitivity to dexmedetomidine, respiratory illness preventing nebulization therapy, Patients refusing consent or Patients requiring immediate epidural blood patch were excluded from study.

Intervention groups
Nebulisation with Dexmeditomidine VS Nebulization with Normal Saline

Main outcome variables
Post Dural Puncture Headache

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260831070845N1**
Registration date: **2026-09-07, 1405/06/16**
Registration timing: **retrospective**

Last update: **2026-09-07, 1405/06/16**
Update count: **0**

Registration date
2026-09-07, 1405/06/16

Registrant information

Name
Ahsan Ali

Name of organization / entity
Pak Emirates Military Hospital

Country
Pakistan

Phone
+92 300 1750592

Email address
drahsan105467@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-01, 1404/09/10

Expected recruitment end date
2026-05-30, 1405/03/09

Actual recruitment start date
2025-12-01, 1404/09/10

Actual recruitment end date
2026-05-30, 1405/03/09

Trial completion date
2026-05-30, 1405/03/09

Scientific title
Nebulized Dexmedetomidine as a Therapeutic Approach for Post-Dural Puncture Headache Following Spinal Anesthesia in Elective Caesarean Delivery

Public title

Dexmedetomidine for Post-dural Puncture Headache

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All Patients aged between 18 and 40 years, who developed PDPH after spinal anesthesia were included in study

Exclusion criteria:

Patients with pre-existing chronic headache or migraine disorder, Cardiac Abnormalities including Atrio-Ventricular blocks and Bundle Branch Blocks, uncontrolled hypertension or neurological disease, hypersensitivity to dexmedetomidine, respiratory illness preventing nebulization therapy, Patients refusing consent or Patients requiring immediate epidural blood patch were excluded from study.

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

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

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The study employed a simple randomization method using a lottery format, focused on individual patients as the unit of randomization. Allocation was carefully concealed to enhance the integrity of the trial, and while stratification was not explicitly noted, it could have been considered for certain baseline variables. The combination of these techniques strengthens the validity of the findings in assessing the efficacy of nebulized dexmedetomidine for post-dural puncture headache management.

Blinding (investigator's opinion)

Double blinded

Blinding description

Our study implemented a comprehensive blinding strategy across all involved parties—from participants to manuscript writers—to safeguard against biases that could compromise the validity of the findings. This thorough approach enhances the reliability of the study results in evaluating the effectiveness of nebulized dexmedetomidine for treating post-dural puncture headaches.

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of CMH Attock

Street address

Combined Military Hospital Attock

City

Attock

Postal code

43600

Approval date

2025-01-10, 1403/10/21

Ethics committee reference number

CMH ATK/EC/01/2025

Health conditions studied

1

Description of health condition studied

Post-dural puncture Headache

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patient Satisfaction score

Timepoint

After 24 Hours, After 48 Hours and 72 Hours

Method of measurement

The VAS is widely recognized for its reliability and sensitivity in measuring pain intensity, making it a suitable choice for assessing the primary outcome of headache relief in this study.

Secondary outcomes

1

Description

Time to Onset of Pain Relief: Measurement: Recorded time (in minutes) from treatment administration to the first report of pain relief by the participant. Overall Satisfaction with Treatment: Measurement: Assessed using a satisfaction scale or questionnaire post-treatment, where participants rate their experience. Adverse Effects: Measurement: Monitoring the incidence of side effects or adverse reactions reported by

participants post-treatment.

Timepoint

Time Intervals for Measuring Secondary OutcomesTime to Onset of Pain Relief: Measurement Points: Immediately post-intervention (0 minutes)15 minutes after intervention30 minutes after intervention Overall Satisfaction with Treatment: Measurement Points:Immediately post-treatment24 hours after intervention Adverse Effects:Measurement Points:Immediately post-treatment24 hours after intervention48 hours after intervention

Method of measurement

Time to Onset of Pain Relief:Measurement Tool: Self-reported time by participants.Method: Participants will record the time (in minutes) from the end of the nebulization treatment until they first experience noticeable pain relief, if any. Overall Satisfaction with Treatment:Measurement Tool: Satisfaction questionnaire (e.g., a Likert scale).Method: Participants will be asked to rate their satisfaction with the treatment on a scale from 1 to 5 (1 = very dissatisfied, 5 = very satisfied) immediately post-treatment and again 24 hours later .Adverse Effects:Measurement Tool: Adverse event reporting form.Method: Participants will be asked to report any side effects or symptoms they experience immediately post-treatment, as well as 24 and 48 hours afterward. Investigators will also monitor for any serious adverse events throughout the study period.

Intervention groups

1

Description

Intervention Group:Details: Participants received nebulized dexmedetomidine at a concentration of 0.5 mg/mL.Method: Administered via a nebulizer.Duration: 10 minutes.Frequency: Once, immediately after the diagnosis of post-dural puncture headache.

Category

Treatment - Drugs

2

Description

Control Group:Details: Participants received a placebo treatment consisting of nebulized saline solution (0.9% sodium chloride).Method: Administered using the same method as the intervention group.Duration: 10 minutes.Frequency: Once, immediately after the diagnosis of post-dural puncture headache.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pak Emirates Military Hospital Rawalpindi

Full name of responsible person

Ahsan Ali

Street address

Flat F-1, Parade Lane Rawalpindi

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Web page address

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Recruitment center

Name of recruitment center

Combined Military Hospital Attock

Full name of responsible person

Lt Col DR Raja Nand

Street address

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City

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Postal code

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drahsan105467@gmail.com

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined Military Hospital Rawalpindi

Full name of responsible person

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Web page address

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
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
Full name of responsible person
Ahsan Ali
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
Specialist
Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further Info please
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
No - There is not a plan to make this available