

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Effects of Three Different Doses of Intrathecal Dexmedetomidine Added to Bupivacaine on effectiveness of Subarachnoid Block in Elective Caesarean Sections: A Prospective Randomized Double-Blind Study

Protocol summary

Study aim

To compare the effects of three different doses (5 µg, 7.5 µg, and 10 µg) of intrathecal dexmedetomidine added to hyperbaric bupivacaine on the effectiveness of subarachnoid block in patients undergoing elective caesarean section.

Design

"A prospective, randomized, double-blind, placebo-controlled clinical trial with four parallel groups."

Settings and conduct

The study will be conducted at the Department of Anaesthesia, DHQ Hospital Batkhela, Malakand, Pakistan. Eligible female patients undergoing elective cesarean section under spinal anesthesia will be randomized into four groups. Perioperative data including block characteristics, analgesia duration, hemodynamic changes, sedation, and adverse effects will be collected and analyzed

Participants/Inclusion and exclusion criteria

Inclusion Criteria • Female patients aged 18–40 years. • ASA physical status I or II. • Scheduled for elective caesarean section under spinal anaesthesia • Willing to provide informed consent Exclusion Criteria • Emergency caesarean sections. • Known fatal anomalies. • Contraindications to spinal anaesthesia (e.g., infection at puncture site, coagulopathy). • Known allergy to dexmedetomidine or bupivacaine. • Significant maternal medical conditions (cardiovascular, neurological, hepatic, or renal disorders).

Intervention groups

Intervention Group 1 (Control group) Intervention Group 2 (Dexmedetomidine 5 µg) Intervention Group 3 (Dexmedetomidine 7.5) Intervention Group 4 (Dexmedetomidine 10 µg

Main outcome variables

Primary outcomes include onset and duration of sensory and motor block and postoperative analgesia. Secondary

outcomes include hemodynamic changes, adverse effects, sedation, and neonatal Apgar scores

General information

Reason for update

Acronym

DDB-CS Trial

IRCT registration information

IRCT registration number: **IRCT20260225068946N1**

Registration date: **2026-07-30, 1405/05/08**

Registration timing: **prospective**

Last update: **2026-07-30, 1405/05/08**

Update count: **0**

Registration date

2026-07-30, 1405/05/08

Registrant information

Name

haider zaman

Name of organization / entity

Health department Khyber pakhtunkhwa

Country

Pakistan

Phone

+92 343 1952928

Email address

haiderzaman311@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-08-12, 1405/05/21

Expected recruitment end date

2026-09-12, 1405/06/21

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of Three Different Doses of Intrathecal Dexmedetomidine Added to Bupivacaine on effectiveness of Subarachnoid Block in Elective Caesarean Sections: A Prospective Randomized Double-Blind Study

Public title
Comparison of Three Different Doses of Dexmedetomidine Added to Spinal Anesthesia for Elective Caesarean Section

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Female patients aged 18–40 years. ASA physical status I or II. Scheduled for elective caesarean section under spinal anaesthesia Willing to provide informed consent
Exclusion criteria:
Emergency caesarean sections. Known fatal anomalies. Contraindications to spinal anaesthesia (e.g., infection at puncture site, coagulopathy). Known allergy to dexmedetomidine or bupivacaine. Significant maternal medical conditions (cardiovascular, neurological, hepatic, or renal disorders).

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

Gender
Female

Phase
4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly assigned to one of four study groups using computer-generated block randomization with a 1:1:1:1 allocation ratio. The randomization sequence was prepared by an independent investigator, and group assignments were concealed in sequentially numbered, opaque, sealed envelopes until participant enrollment.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and outcome assessors were blinded to group allocation. The intrathecal study drug was prepared by an independent anesthetist not involved in patient management or outcome assessment. All study solutions had identical appearance and volume, ensuring

that participants and the anesthesiologist administering the drug remained unaware of treatment allocation until completion of data collection.

Placebo
Used

Assignment
Parallel

Other design features
Prospective, randomized, double-blind, parallel-group, controlled clinical trial with four intervention arms comparing three doses (5 µg, 7.5 µg, and 10 µg) of intrathecal dexmedetomidine added to hyperbaric bupivacaine with a control group receiving hyperbaric bupivacaine alone.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of superior university
Street address
Jarbat, Julagram tehsil batkhela, district malakand kpk Pakistan
City
Batkhela
Postal code
23020
Approval date
2025-10-10, 1404/07/18
Ethics committee reference number
IRB/FAHS/Allied/10/25/MS/AHS-3837

Health conditions studied

1

Description of health condition studied
Obstetric patients undergoing elective cesarean section under spinal anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Onset and duration of sensory block, onset and duration of motor block, and duration of postoperative analgesia following spinal anesthesia
Timepoint
Assessment will be performed from the time of spinal anesthesia administration until 24 hours after surgery
Method of measurement
Sensory block will be assessed using the pinprick method and motor block using the Modified Bromage scale.

Duration of analgesia will be measured from the time of spinal anesthesia administration until the first request for rescue analgesia

Secondary outcomes

1

Description

Hemodynamic changes (heart rate and blood pressure), incidence of adverse effects including hypotension, bradycardia, nausea, vomiting, shivering, and sedation level will be assessed. Neonatal outcomes will be evaluated using Apgar scores at 1 and 5 minutes.

Timepoint

During the intraoperative period and within the first 24 hours after surgery

Method of measurement

Heart rate and blood pressure will be recorded using standard non-invasive monitoring. Adverse effects including hypotension, bradycardia, nausea, vomiting, and shivering will be documented. Sedation will be assessed using the Ramsay Sedation Scale. Neonatal condition will be evaluated using Apgar scores at 1 and 5 minutes after birth

Intervention groups

1

Description

Control group: (Intrathecal hyperbaric bupivacaine 10 mg with placebo (normal saline))

Category

Placebo

2

Description

Intervention group: (Intrathecal hyperbaric bupivacaine 10 mg + dexmedetomidine 5 µg)

Category

Treatment - Drugs

3

Description

Intervention group: (Intrathecal hyperbaric bupivacaine 10 mg + dexmedetomidine 7 µg)

Category

Treatment - Drugs

4

Description

Intervention group: (Intrathecal hyperbaric bupivacaine 10 mg + dexmedetomidine 10 µg)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Anaesthesia, DHQ Hospital Batkhela, Malakand, Khyber Pakhtunkhwa, Pakistan

Full name of responsible person

haider zaman

Street address

Jarbat, Julagram tehsil batkhela

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Email

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Superior university lahore

Full name of responsible person

+92 306 7898340

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Superior University Main Campus, Main Raiwind Road, Lahore, Punjab, Pakistan

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Lahore

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Email

Sarmad.siddique@superior.edu.pk

Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Superior university lahore

Proportion provided by this source

40

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

Superior university lahore

Full name of responsible person

haider zaman

Position

MS scholar

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

Jarbat, Julagram tehsil batkhela

City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Health department Khyber pakhtunkhwa

Full name of responsible person

Haider Zaman

Position

Anesthesia technologist

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Position

Anesthesia technologist

Latest degree

Master

Other areas of specialty/work

Anesthesiology

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Fax**Email**

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified Clinical Trial Dataset and Study Documents" Details: "The dataset will include anonymized demographic characteristics, clinical observations, sensory and motor block parameters, duration of analgesia, hemodynamic measurements, adverse effects, sedation scores, and neonatal Apgar scores collected during the study. Additional documents may include the study protocol, statistical analysis plan, and final study results. All shared data will be de-identified to protect participant confidentiality

When the data will become available and for how long

The data will become available after completion of the study, final data analysis, and publication of the results. The data may be available for a period of 5 years after publication upon reasonable request and approval from the principal investigator

To whom data/document is available

The data/documents will be available to qualified researchers, academic institutions, and scientific reviewers upon reasonable request and approval from the principal investigator and relevant ethical authorities. Access will be provided only for legitimate research

purposes while maintaining participant confidentiality.

Under which criteria data/document could be used

The data/documents may be used for scientific research, academic purposes, systematic reviews, and secondary analyses related to obstetric anesthesia, spinal anesthesia, and intrathecal dexmedetomidine. Requests will be evaluated based on scientific merit, ethical approval (if required), and assurance of maintaining participant confidentiality.”

From where data/document is obtainable

The data/documents can be obtained from the principal investigator of the study upon reasonable request. Access will be provided after review and approval of the request, in accordance with ethical requirements and

data confidentiality policies.

What processes are involved for a request to access data/document

A formal request should be submitted to the principal investigator describing the purpose of data use. The request will be reviewed for scientific validity, ethical compliance, and confidentiality requirements. After approval, de-identified data/documents will be shared through a secure method with the requester

Comments

No additional comments. All shared data and documents will be de-identified to ensure participant confidentiality and will be made available only for legitimate scientific and academic purposes following ethical approval and the consent of the principal investigator.