Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Recruitment complete

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
City
Batkhela
Postal code
23020
Phone
+92 343 1952928
Email
haiderzaman311@gmail.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Superior university lahore
Full name of responsible person
+92 306 7898340
Street address
Superior University Main Campus, Main Raiwind Road, Lahore, Punjab, Pakistan
City
Lahore
Postal code
23020
Phone
+92 343 1952928
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
Batkhela

Province
Khyber Pakhtunkhwa

Postal code
23020

Phone
+92 343 1952928

Email
haiderzaman311@gmail.com

Web page address

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

Street address
Post office dehri julagram tehsil batkhela district malakand kpk pakistan

City
Batkhela malakand

Province
Khyber pakhtunkhwa

Postal code
23020

Phone
+92 343 1952928

Fax

Email
haiderzaman311@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Health department Khyber pakhtunkhwa

Full name of responsible person
Haider Zaman

Position
Anesthesia technologist

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Street address
Post office dehri julagram tehsil batkhela district malakand kpk pakistan

City
Batkhela Malakand

Province
Khyber pakhtunkhwa

Postal code
23020

Phone
+92 343 1952928

Fax

Email
haiderzaman311@gmail.com

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.