Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Safety and Efficacy of Intrathecal Combination of Dexmedetomidine and Bupivacaine for Postoperative Pain Management in Cesarean Section Patients: Randomized Controlled Trial

Protocol summary

Study aim
Determining the safety and efficacy of intrathecal combination of Dexmedetomidine and Bupivacaine for postoperative pain management in C/S patients

Design
A double blinded randomized clinical trial by block method with one control and three intervention groups (each: n=50)

Settings and conduct
Eligible parturients based on the entry criteria will be randomly assigned into one of the intervention (A, B, C) or control (D) groups using blocked randomization and sealed envelopes after signing an informed written consent. Spinal anesthesia will be performed using a standard protocol in all patients. A researcher-made checklist will be used as the data collection tool. Also, the post-surgery outcomes during the first 48 hours after the operation including the times of painkiller request along with the expressed pain intensity (based of the visual analogue scale) will be recorded. Data analysis will be done using SPSS software

Participants/Inclusion and exclusion criteria
Pregnant women between 18 and 45 years old Candidate for non-emergency C/S Spinal anesthesia as the method of choice Informed consent from the patient

Intervention groups
A: bupivacaine + Dex. 5 mcg B: bupivacaine + Dex. 7.5 mcg C: bupivacaine + Dex. 10 mcg D: control: bupivacaine + physiological serum (volume equivalent to dexmedetomidine)

Main outcome variables
Time to request of first additional analgesic Pain score at specified times after surgery General consumption of painkillers within 48 hours after surgery The duration of maintaining the sensory and motor block Time to remove the effect of sensory and motor block Possible complications related to the intervention

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20241116063729N1**
Registration date: **2025-04-09, 1404/01/20**
Registration timing: **prospective**

Last update: **2025-04-09, 1404/01/20**
Update count: **0**

Registration date
2025-04-09, 1404/01/20

Registrant information

Name
Afsaneh HashemiDoust

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-04-21, 1404/02/01

Expected recruitment end date
2025-08-22, 1404/05/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and Efficacy of Intrathecal Combination of Dexmedetomidine and Bupivacaine for Postoperative Pain Management in Cesarean Section Patients: Randomized Controlled Trial

Public title
Intrathecal administration of combination of dexmedetomidine and bupivacaine for postoperative pain relief in elective caesarean section patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for elective cesarean section Spinal anesthesia as the method of choice for cesarean section Written consent from the patient to participate in the study No history of allergy to the medications used in the study Lack of blood, infectious, or neurological disorders that may cause problems with spinal anesthesia

Exclusion criteria:
Need for changing the anesthesia method during surgery Allergic reaction/hypersensitivity to the medications used in this study

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description
Using the following website: https://www.sealedenvelope.com/simple-randomiser/v1/lists Block randomization will be performed in 4 and 8 block sizes: Block sizes: 4,8 Actual list length: 204 block identifier, block size, sequence within block, treatment

Blinding (investigator's opinion)
Double blinded

Blinding description
For concealment, opaque, sealed, sequentially numbered envelopes are used so that the assigned group is not known before the individual is assigned. In this study, the patient and the analyst are blind to the assignment, but the anesthesiologist in charge is fully aware of the assignment so that he or she can deal with and treat any complications that may arise. Considering that the patient is positioned lying on their side, and the medication is administered from the back in the intervertebral space of the lower back, which is out of the patient's view, and also due to the patient's lack of precise knowledge about the content of the syringe, the patient will remain blind to their allocation to any of the study groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committees of Imam Reza Hospital Educational, Research and Treatment Center-Mashhad

Street address
Ebnesina Ave., Daneshgah Blvd., Mashhad city

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2024-10-13, 1403/07/22

Ethics committee reference number
IR.MUMS.IRH.REC.1403.156

Health conditions studied

1

Description of health condition studied
pain

ICD-10 code
R52

ICD-10 code description
Pain, unspecified

Primary outcomes

1

Description
Pain Intensity

Timepoint
at 2,4,6,12, and 24 hours after operation

Method of measurement
The patient is asked to rate her pain based on the VAS scale (0 to 10)

Secondary outcomes

1

Description
Analgesic Consumption

Timepoint
As per complain from pain or at defined time points
Method of measurement
The cumulative analgesic consumption during the 24 h after surgery will be recorded.

2

Description
Possible adverse effects of the intervention
Timepoint
During the 24 h after surgery
Method of measurement
Adverse effects including the hypotension, bradycardia, gastrointestinal symptoms, allergic reactions, and injection site reaction will be recorded.

Intervention groups

1

Description
Intervention group A : Bupivacaine (chemical formula C18H28N2O) from 4 ml vials containing 5 mg/ml,(manufactured by Myungmoon Pharmaceutical Company) 2.5 cc (equivalent to 12.5 mg) + Dexmedetomidine (chemical formula C13H16N2, 2 ml vials containing 100 micrograms per ml, manufactured by Exir Borujerd Pharmaceutical Company) 0.2 cc (equivalent to 5 micrograms) + 0.2 cc of 0.9% normal saline serum .The total volume will be 2.9 cc, which will be injected once into the spinal space between the L4 and L5 vertebrae.
Category
Treatment - Drugs

2

Description
Intervention group B: Bupivacaine (chemical formula C18H28N2O) from 4 ml vials containing 5 mg/ml,(manufactured by Myungmoon Pharmaceutical Company) 2.5 cc (equivalent to 12.5 mg) + Dexmedetomidine (chemical formula C13H16N2, 2 ml vials containing 100 micrograms per ml, manufactured by Exir Borujerd Pharmaceutical Company) 0.3cc (equivalent to 5 micrograms) + 0.1cc of 0.9% normal saline serum .The total volume will be 2.9 cc, which will be injected once into the spinal space between the L4 and L5 vertebrae.
Category
Treatment - Drugs

3

Description
Intervention group C: Bupivacaine (chemical formula C18H28N2O) from 4 ml vials containing 5 mg/ml,(manufactured by Myungmoon Pharmaceutical Company) 2.5 cc (equivalent to 12.5 mg) + Dexmedetomidine (chemical formula C13H16N2, 2 ml vials containing 100 micrograms per ml, manufactured by Exir Borujerd Pharmaceutical Company) 0.4cc (equivalent to 5 micrograms) + Without 0.9% normal saline serum .The total volume will be 2.9 cc, which will be injected once into the spinal space between the L4 and L5 vertebrae.
Category
Treatment - Drugs

4

Description
Control group D:Bupivacaine (chemical formula C18H28N2O) from 4 ml vials containing 5 mg/ml,(manufactured by Myungmoon Pharmaceutical Company) 2.5 cc (equivalent to 12.5 mg) + Without Dexmedetomidine + 0.4 cc of 0.9% normal saline serum .The total volume will be 2.9 cc, which will be injected once into the spinal space between the L4 and L5 vertebrae.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital, Mashhad University of Medical Sciences
Full name of responsible person
Afsaneh Hashemi Doust
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name

Safety and Efficacy of Intrathecal Combination of Dexmedetomidine and Bupivacaine for Postoperative Pain Management in Cesarean Section Patients: Randomized Controlled Trial

Grant code / Reference number

4020161

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

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Alipour

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Associate Professor

Latest degree

Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Afsaneh HashemiDoust

Position

Resident

Latest degree

Medical doctor

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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

Sharing the data will be possible upon reasonable request from the project manager

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

The methodology and finding of the current study will be published as a scientific paper in scientific journals.

When the data will become available and for how long

As soon as the accepted manuscript becomes online

To whom data/document is available

Publicly

Under which criteria data/document could be used

Under the regulations of the journal

From where data/document is obtainable

The journal

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

Email request from the officials

Comments