Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the Effect of Intraperitoneal Dexmedetomidine and Normal Saline on Postoperative Pain Severity after Elective Cesarean Section in Pregnant Women

Protocol summary

Study aim

To evaluate the effect of intraperitoneal dexmedetomidine on postoperative pain severity after elective cesarean section

Design

Randomized, double blind, parallel group phase 3 clinical trial with 60 participants using computer generated randomization and allocation concealment

Settings and conduct

The present study is conducted at Kamali Hospital in Karaj on pregnant women who are candidates for elective cesarean section. All patients receive standard spinal anesthesia, and complete monitoring of vital signs is performed throughout the surgery. In the intervention group, dexmedetomidine at a dose of 1 µg/kg, diluted in 40 mL of normal saline, is administered intraperitoneally at the end of surgery after uterine closure. In the control group, 40 mL of normal saline is administered in the same manner. The study drugs are prepared in identical syringes by an independent anesthesiologist, and participants, clinical staff, and outcome assessors are blinded to group allocation (double-blind). Postoperatively, pain severity is assessed at predefined time intervals, and analgesic consumption, vital signs, and potential adverse effects are recorded and compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18 to 40 years undergoing elective cesarean section under spinal anesthesia with ASA class II and second cesarean delivery; exclusion criteria include emergency cesarean section, preterm pregnancy, underlying systemic disease, allergy to dexmedetomidine, use of analgesics or sedatives within 24 hours before surgery, and refusal to participate

Intervention groups

Intervention group receives intraperitoneal dexmedetomidine at a dose of 1 microgram per kilogram diluted in 40 milliliters normal saline; control group receives 40 milliliters normal saline intraperitoneally

Main outcome variables

Postoperative pain severity based on Visual Analog Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260216068880N1**
Registration date: **2026-03-31, 1405/01/11**
Registration timing: **prospective**

Last update: **2026-03-31, 1405/01/11**
Update count: **0**

Registration date

2026-03-31, 1405/01/11

Registrant information

Name

Fatemeh Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

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moradi.fatemeh2020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-04-04, 1405/01/15

Expected recruitment end date

2026-10-07, 1405/07/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Intraperitoneal Dexmedetomidine and Normal Saline on Postoperative Pain Severity after Elective Cesarean Section in Pregnant Women

Public title
Effect of Intraperitoneal Dexmedetomidine on Postoperative Pain after Cesarean Section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18 to 40 years Undergoing elective cesarean section under spinal anesthesia ASA physical status II Second cesarean delivery Ability to understand and report pain using Visual Analog Scale Provision of written informed consent
Exclusion criteria:
Emergency cesarean section Preterm pregnancy Age below 18 or above 40 years History of allergy to dexmedetomidine Underlying systemic diseases Use of analgesics or sedatives within 24 hours before surgery Refusal to participate
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomly allocated into two groups using a computer-generated random sequence Randomization will be performed at the individual level using simple randomization Allocation concealment will be ensured using sequentially numbered, sealed opaque envelopes A researcher not involved in patient care or outcome assessment will generate the random sequence and prepare the envelopes.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted as a double-blind randomized clinical trial Participants, clinical care providers, investigators, and outcome assessors will be blinded to group allocation Study medications will be prepared by an anesthesiologist not involved in patient care or outcome assessment and labeled with coded identifiers Both dexmedetomidine and normal saline will be prepared in identical syringes with the same volume and appearance Group allocation codes will be concealed until completion of data analysis.
Placebo
Used
Assignment
Parallel
Other design features
This study is a randomized, double-blind, parallel-group clinical trial conducted as a pilot study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Alborz University of Medical Sciences
Street address
Alborz University of Medical Sciences, Taleghani Boulevard, Taleghani Square, Karaj, Iran
City
Karaj
Province
Alborz
Postal code
3149779453
Approval date
2025-05-26, 1404/03/05
Ethics committee reference number
IR.ABZUMS.REC.1404.241

Health conditions studied

1

Description of health condition studied
Postoperative pain after cesarean section
ICD-10 code
O82
ICD-10 code description
Encounter for cesarean delivery without indication

Primary outcomes

1

Description
Postoperative pain severity after cesarean section
Timepoint
Immediately after recovery and every 15 minutes up to 3 hours after surgery
Method of measurement

Visual Analogue Scale for pain assessment

Secondary outcomes

1

Description
Postoperative opioid consumption
Timepoint
During recovery period up to 3 hours after surgery
Method of measurement
Total dose of administered pethidine recorded in milligrams

2

Description
Postoperative blood pressure
Timepoint
Before intervention and every 15 minutes up to 3 hours after surgery
Method of measurement
Measured using a standard calibrated blood pressure monitoring device

3

Description
Arterial oxygen saturation
Timepoint
Before intervention and every 15 minutes up to 3 hours after surgery
Method of measurement
Measured using a standard pulse oximeter

4

Description
Postoperative nausea and vomiting
Timepoint
During recovery period up to 3 hours after surgery
Method of measurement
Clinical assessment based on presence or absence of nausea and vomiting

5

Description
Postoperative shivering
Timepoint
During recovery period up to 3 hours after surgery
Method of measurement
Clinical assessment based on presence or absence of shivering

Intervention groups

1

Description
Intervention group: Dexmedetomidine, manufactured by Shahid Ghazi Pharmaceutical Company (Tabriz, Iran), administered intraperitoneally at a dose of 1 µg/kg, diluted in 40 mL of normal saline, and given at the end of surgery after uterine closure
Category
Treatment - Drugs

2

Description
Control group: Intraperitoneal administration of 40 milliliters normal saline (Shahid Ghazi Pharmaceutical Company, Tabriz, Iran) at the end of surgery after uterine closure
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali Hospital
Full name of responsible person
Fatemeh Moradi
Street address
No. 1, Shahid Beheshti Blvd., Kamali Hospital, Karaj
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Vice Chancellor for Research and Technology
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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
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Fatemeh Moradi
Position
General medical student
Latest degree
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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
Deidentified individual participant data including demographic characteristics, clinical variables, and outcome measures; study protocol; statistical analysis plan; informed consent form; clinical study report; analysis codes; and data dictionary
When the data will become available and for how long
Data will be available starting 6 months after publication of the study results and will remain accessible for up to 5 years

To whom data/document is available

Researchers affiliated with academic or research institutions upon reasonable request

Under which criteria data/document could be used

Data will be shared for scientific research purposes with a methodologically sound proposal and after approval by the principal investigator; data use agreement is required

From where data/document is obtainable

Requests should be sent to the principal investigator via email at moradi.fatemeh2020@gmail.com

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

Requests will be reviewed within 2 weeks and eligible applicants will receive access within 1 month after approval

Comments

All shared data will be fully deidentified to ensure participant confidentiality