Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of the Effectiveness of Intrathecal Fentanyl and Dexmedetomidine as Adjuvants to Ropivacaine in Spinal Anesthesia for Cesarean Section

Protocol summary

Study aim

This study aims to compare the effectiveness of intrathecal fentanyl and dexmedetomidine as adjuvants to ropivacaine in spinal anesthesia for cesarean section.

Design

Randomized, double-blind, parallel-group, single-centre phase 3 trial with concealed allocation.

Settings and conduct

This study is conducted in the operating room and postnatal ward of Imam Khomeini, Golestan, and Razi hospitals in Ahvaz. Eligible women, after obtaining consent, are randomly allocated to two groups with concealed allocation (sealed opaque envelopes). An independent person (with no role in assessments) prepares the intrathecal solutions with a completely identical appearance. This study is double-blind; the participants, outcome assessors, and data analyst are unaware of the group allocation, and the analyst remains blinded until the completion of the primary analysis.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 40 years, singleton term pregnancy with gestational age of 37 weeks or more, candidate for elective cesarean section under spinal anesthesia, American Society of Anesthesiologists physical status class 1 or 2, body mass index less than 35, willingness and ability to provide written informed consent. Exclusion criteria: Known allergy or hypersensitivity to ropivacaine, fentanyl, or dexmedetomidine; pre-existing cardiovascular disease; placental abnormalities such as placenta previa or placental abruption; known fetal abnormalities or fetal distress.

Intervention groups

Group 1: Intrathecal injection of 15 mg ropivacaine (0.5%, 2.5 mL; Bioindustria L.I.M) plus 15 µg fentanyl (Daroupakhsh Co.) for spinal anesthesia during elective cesarean section. Group 2 : Intrathecal injection of 15 mg ropivacaine (0.5%, 2.5 mL; Bioindustria L.I.M) plus 5 µg dexmedetomidine (Exir Pharmaceutical Co.) for spinal anesthesia during elective cesarean section.

Main outcome variables

Duration of postoperative analgesia; Onset time of sensory block; Systolic blood pressure; Heart rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210222050463N5**
Registration date: **2026-06-20, 1405/03/30**
Registration timing: **prospective**

Last update: **2026-06-20, 1405/03/30**
Update count: **0**

Registration date

2026-06-20, 1405/03/30

Registrant information

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Name of organization / entity

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-07-01, 1405/04/10

Expected recruitment end date

2026-12-31, 1405/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Intrathecal Fentanyl and Dexmedetomidine as Adjuvants to Ropivacaine in Spinal Anesthesia for Cesarean Section

Public title

Fentanyl versus Dexmedetomidine Added to Spinal Anesthesia for Pain Relief in Cesarean Section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 40 years (including both limits). Full-term singleton pregnancy with gestational age of 37 weeks or more. Candidate for elective cesarean section under spinal anesthesia. Physical status Class I or II according to the American Society of Anesthesiologists (ASA) classification. Body mass index (BMI) less than 35 kg/m². Willingness and mental/legal ability to provide written informed consent.

Exclusion criteria:

Known allergy or hypersensitivity to ropivacaine, fentanyl, or dexmedetomidine. Pre-existing cardiovascular disease (e.g., uncontrolled hypertension, heart failure, arrhythmia). Placental abnormalities such as placenta previa or placental abruption. Known fetal abnormalities or fetal distress.

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

An independent statistician who has no role in patient recruitment, outcome assessment, or data analysis generates a simple random allocation sequence of 120 codes using R statistical software (version 4.2 or higher) and the sample function. In this sequence, 60 codes are assigned to the fentanyl group and 60 codes to the dexmedetomidine group (1:1 allocation ratio). No stratification (e.g., blocking or matching) is applied in this process. The statistician then prepares one opaque, sealed, and non-transparent envelope for each of the 120 potential participants. Inside each envelope, a sheet of paper containing the name of the allocated group (fentanyl or dexmedetomidine) is placed, and on the outside of each envelope, a sequential number from 1 to 120 is written, such that the envelope number corresponds to the order of the generated random sequence. All envelopes are sealed and stored in a locked cabinet at the study site. When a pregnant woman meets the inclusion criteria and signs the written informed consent, the next envelope with the lowest number among the unopened envelopes is opened by a nurse or an anesthesiologist who is not involved in data collection or outcome assessment. Immediately based on the envelope content, the intrathecal drug (ropivacaine with either fentanyl or dexmedetomidine) is prepared and injected. Thus, until the moment of envelope opening, none of the individuals involved in the study (participant, outcome assessor, and data analyst) are aware of the allocated group, and allocation concealment is maintained for all participants.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study in which the participants, the principal investigator, the outcome assessors, and the data analyst are all masked to treatment allocation. An independent biostatistician will generate the randomization sequence and prepare sequentially numbered, opaque, sealed envelopes, each containing the group assignment. After a participant has given written informed consent, a designated anesthesia provider (who is not involved in any postoperative data collection, outcome assessment, or data analysis) will open the next envelope and prepare the intrathecal solution according to the assignment. Both study drugs (ropivacaine with fentanyl and ropivacaine with dexmedetomidine) are colorless liquids and will be drawn up into identical syringes with the same total volume, so that the participant cannot distinguish them by appearance. The anesthesia provider who prepares the injection will not participate in subsequent patient care or assessment. All postoperative evaluations (pain scores, hemodynamic measurements, and adverse event recording) will be performed by investigators who were not present during drug preparation and are unaware of the group assignment. The data will be entered into the database using coded group labels, and the statistician performing the analysis will remain blind until the primary analysis is complete. No Data and Safety Monitoring Board is established, as this is a single-centre, phase 3 trial with short follow-up and well-known drugs, but if any interim analysis is requested, the analyst will work on masked data.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd, Ahvaz, Khuzestan Province, Iran

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6135715794

Approval date
2026-02-14, 1404/11/25

Ethics committee reference number
IR.AJUMS.REC.1404.626

Health conditions studied

1

Description of health condition studied
Postoperative pain following cesarean section under spinal anesthesia.

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Duration of postoperative analgesia

Timepoint
From the end of the intrathecal injection until the first request for rescue analgesic, assessed continuously during the first 48 hours after surgery.

Method of measurement
0 to 10 Visual Analogue Scale (VAS) and stopwatch.

Secondary outcomes

1

Description
Onset time of sensory block

Timepoint
Every 2 minutes after the intrathecal injection until the sensory block reaches the fourth thoracic dermatome and then every 15 minutes until the end of surgery.

Method of measurement
Loss of pinprick sensation will be tested with a short-beveled needle along the midclavicular line. The time will be recorded by a blinded outcome assessor using a stopwatch.

2

Description
Systolic blood pressure

Timepoint
At baseline before spinal anesthesia, immediately after the intrathecal injection, then at 2, 4, 6, 8, 10, 15, 20, 30 minutes and every 15 minutes until the end of surgery, and at 0, 6, 12, 24, 36, and 48 hours postoperatively.

Method of measurement
Non-invasive automated oscillometric blood pressure monitor (calibrated sphygmomanometer).

3

Description
Heart rate

Timepoint
At baseline before spinal anesthesia, immediately after the intrathecal injection, then at 2, 4, 6, 8, 10, 15, 20, 30 minutes and every 15 minutes until the end of surgery, and at 0, 6, 12, 24, 36, and 48 hours postoperatively.

Method of measurement
Heart rate will be obtained from the continuous electrocardiogram or pulse oximeter, recorded simultaneously with each blood pressure measurement.

Intervention groups

1

Description
Intervention group 1: Intrathecal injection of 2.5 mL (15 mg) of 0.5% ropivacaine (Bioindustria L.I.M) plus 0.5 mL (15 µg) of fentanyl (Daroupakhsh Co.), prepared as a single solution with a total volume of 3 mL, administered once immediately before cesarean section.

Category
Treatment - Drugs

2

Description
Intervention group 2: Intrathecal injection of 2.5 mL (15 mg) of 0.5% ropivacaine (Bioindustria L.I.M) plus 0.5 mL (5 µg) of dexmedetomidine (Exir Pharmaceutical Co.), prepared as a single solution with a total volume of 3 mL, administered once immediately before cesarean section.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Ali Khalafi

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Imam Khomeini Hospital, 24 Metri Street (Bagh-e Moin), Shohada Square, Ahvazian Street, Ahvaz, Khuzestan Province, Iran
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2

Recruitment center
Name of recruitment center
Golestan Hospital
Full name of responsible person
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3

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Ahvaz 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
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Full name of responsible person
Nooshin Sarvi
Position
Instructor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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

All de-identified individual participant data (IPD) collected during the trial, including baseline characteristics, intraoperative and postoperative pain scores, hemodynamic measurements, adverse event records, sedation scores, neonatal Apgar scores, and time-to-event variables. The following supporting documents will also be shared: the full study protocol, the statistical analysis plan (SAP), the informed consent form (ICF) template, the clinical study report (CSR), the analytic code used for the primary analysis, and the data dictionary.

When the data will become available and for how long

Data and documents will become available starting 6 months after the publication of the primary results in a peer-reviewed journal, and will remain accessible for a period of 3 years thereafter.

To whom data/document is available

Access is open to researchers based in academic institutions and not-for-profit organisations who submit a methodologically sound research proposal. Requests from commercial entities will be considered only if the proposed analysis has the potential to significantly improve patient care or public health, and such requests will require additional approval from the university ethics committee.

Under which criteria data/document could be used

Data may be used only for the purposes described in the approved proposal. Each request must include a clear description of the research question, the planned statistical analysis, and the intended dissemination of results. The principal investigator and the institutional ethics committee will review all requests. Criteria for approval include scientific merit, consistency with the ethical principles of the original study, and compliance with data protection regulations. Successful applicants must sign a data-sharing agreement that prohibits any attempt to re-identify participants, redistribution of the data to third parties, or use for commercial profit without prior written permission.

From where data/document is obtainable

Requests should be submitted by email to the principal investigator, Ali Khalafi (khalafi-a@ajums.ac.ir), with the subject line “Data Sharing Request: IRCT[…….]”. The application must include a short proposal. After approval,

the de-identified dataset and requested documents will be transferred via a secure, password-protected cloud repository or encrypted email, according to the institution’s data transfer policy. No postal or fax-based distribution is planned.

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

The applicant sends an email to the principal investigator (khalafi-a@ajums.ac.ir) with the subject “Data Sharing Request: IRCT[…]” and attaches a short proposal describing the research question, analysis plan, and dissemination intentions. Within 4–6 weeks, the principal investigator and the institutional ethics committee will review the request for scientific merit, ethical soundness, and compliance with data protection regulations. If approved, the applicant will receive a data-sharing agreement that must be signed and returned. The agreement prohibits re-identification, redistribution to third parties, and commercial use without permission. Within 2 weeks after the signed agreement is received, the de-identified dataset and requested documents will be transferred via a secure, password-protected cloud link or encrypted email. The total time from initial request to data receipt is typically 8–12 weeks.

Comments