Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A comparison study of bupivacaine 0.25% with fentanyl versus bupivacaine 0.25% with Dexmedetomidine in TAP block for postoperative analgesia following a cesarean section.

Protocol summary

Study aim

This randomized double-blind trial compares dexmedetomidine and fentanyl as adjuvants to bupivacaine in ultrasound-guided bilateral transversus abdominis plane block for pain control after elective cesarean section under general anesthesia. Outcomes include postoperative pain, rescue analgesia request, 24-hour opioid use, maternal satisfaction, and adverse events.

Design

This study is a prospective, randomized, double-blind, parallel-group clinical trial. Eligible participants will be randomly assigned in a 1:1 ratio to one of two intervention groups. The study will compare dexmedetomidine versus fentanyl as adjuvants to bupivacaine in ultrasound-guided bilateral transversus abdominis plane block after elective cesarean section under general anesthesia.

Settings and conduct

The trial will be conducted in the operating room and postoperative ward. Eligible women will be randomized. Blinded staff will use coded syringes for ultrasound-guided block.

Participants/Inclusion and exclusion criteria

Participants are pregnant women aged 18–45 undergoing elective cesarean section under general anesthesia. Inclusion: ASA physical status I or II, singleton pregnancy, ability to report pain via Visual Analogue Scale, and written informed consent. Exclusion: emergency cesarean, ASA III+, concomitant surgery, major complications, drug allergy, coagulation disorder, infection, chronic opioid use, chronic pain, failed block, withdrawal, or incomplete data.

Intervention groups

Eligible participants will be randomized to two groups receiving ultrasound-guided bilateral transversus abdominis plane block with bupivacaine plus dexmedetomidine or fentanyl.

Main outcome variables

The primary outcome is postoperative pain intensity at 6 hours using the Visual Analogue Scale. Secondary outcomes include other pain times, rescue analgesia, opioid use, maternal satisfaction, and adverse events.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260208068799N1**
Registration date: **2026-06-08, 1405/03/18**
Registration timing: **prospective**

Last update: **2026-06-08, 1405/03/18**
Update count: **0**

Registration date

2026-06-08, 1405/03/18

Registrant information

Name

Mina Vishteh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-07-02, 1405/04/11

Expected recruitment end date

2027-07-02, 1406/04/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison study of bupivacaine 0.25% with fentanyl versus bupivacaine 0.25% with Dexmedetomidine in TAP block for postoperative analgesia following a cesarean section.

Public title

Bupivacaine, fentanyl, and dexmedetomidine in cesarean section.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women aged 18 to 45 years. Scheduled for elective cesarean section under general anesthesia. American Society of Anesthesiologists physical status class I or II. Singleton pregnancy. No major obstetric or surgical complication before the operation. Cesarean section performed without any concomitant surgery or additional surgical intervention. Ability to understand and report pain intensity using the visual analogue scale, VAS. Provision of written informed consent to participate in the study.

Exclusion criteria:

Withdrawal of consent or unwillingness to continue participation at any stage of the study. American Society of Anesthesiologists physical status class III or higher. Emergency cesarean section. Major intraoperative complications, including severe bleeding, visceral injury, hemodynamic instability, or the need for unusual therapeutic intervention. Requirement for concomitant surgery or any additional surgical intervention during cesarean section. Known allergy or contraindication to bupivacaine, dexmedetomidine, fentanyl, or any other medication used in the study. Coagulation disorders or current use of anticoagulant medications. Infection at the TAP block injection site. History of chronic opioid use, sedative use, or long-term analgesic medication use. Presence of chronic abdominal, pelvic, or low back pain that may interfere with postoperative pain assessment. History of psychiatric or cognitive disorders affecting the patient’s ability to report pain. Inability to understand or use the visual analogue scale, VAS. Failed or incomplete TAP block based on clinical assessment by the anesthesiologist. Serious complications related to general anesthesia or regional block requiring a major change in the patient’s treatment plan. Incomplete data regarding the primary outcome of the study.

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

After eligibility assessment and obtaining written informed consent, eligible participants will be randomly allocated to one of the two study groups in a 1:1 ratio. The random allocation sequence will be generated by an independent person who is not involved in patient recruitment, intervention administration, outcome assessment, or data analysis, using a computer-generated random number sequence. Block randomization with variable block sizes will be used to maintain balance between the two study groups. Allocation concealment will be ensured using sequentially numbered, opaque, sealed, light-proof envelopes. Each envelope will be opened only after the participant has been definitively enrolled in the study and immediately before preparation of the study medication. Study medications will be prepared by an independent person and provided in identical syringes with coded labels, similar in appearance and volume. Participants, the anesthesiologist performing the TAP block, postoperative care staff, outcome assessors, and the statistician will remain blinded to group allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a double-blind randomized clinical trial. Participants, the anesthesiologist performing the TAP block, postoperative care staff, outcome assessors, and the statistician will remain unaware of participants’ group allocation. The allocation sequence and group codes will be generated and kept by an independent person who is not involved in patient care, intervention administration, data collection, outcome assessment, or statistical analysis. Study medications will be prepared by the same independent person, or by a trained pharmacist/nurse who has no role in patient assessment or data analysis. For each participant, the study medication will be prepared according to the randomization code in identical syringes with similar volume, appearance, and coded labeling. The syringes will be labeled only with the study code and participant number, and the name of the medication will not be written on the syringe. In both groups, the final injected volume for the TAP block will be identical, and the study solutions will not be distinguishable by appearance. Bilateral TAP block will be performed in both groups using the same technique, at the same anatomical site, with the same injection volume, and under ultrasound guidance. Therefore, the participant, the anesthesiologist performing the block, and the outcome assessor will not be able to identify the treatment group. Assessment of pain intensity, duration of analgesia, time to first request

for rescue analgesia, rescue analgesic consumption, maternal satisfaction, and adverse events will be performed by an assessor blinded to group allocation. Data will be entered into the statistical software using coded group labels, such as Group A and Group B, and the statistician will remain blinded to the actual intervention assigned to each group until completion of the primary analysis. Allocation codes will remain confidential until completion of data collection and primary statistical analysis. In case of a serious adverse event or emergency situation in which knowledge of the administered study medication is necessary for patient management, unblinding for that individual participant will be permitted by the principal investigator or the study safety supervisor. The reason, time, and person responsible for unblinding will be documented and reported.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

School of Medicine - Shahid Beheshti University of Medical Sciences (Research Ethics Committee)

Street address

Shahid Chamran Highway- Evin- next to Taleghani Hospital- Medical School- third floor

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2026-02-05, 1404/11/16

Ethics committee reference number

IR.SBMU.MSP.REC.1404.686

Health conditions studied

1

Description of health condition studied

cesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Postoperative pain intensity will be assessed using the Visual Analogue Scale, VAS, at 6 hours after cesarean section. The scale ranges from 0 to 10, where 0 indicates no pain and 10 indicates the worst imaginable pain. The primary outcome will be the comparison of the mean VAS score at 6 hours postoperatively between the two intervention groups.

Timepoint

Postoperative pain intensity will be assessed at 6 hours after completion of cesarean section and performance of the ultrasound-guided bilateral TAP block.

Method of measurement

Postoperative pain intensity will be measured using the Visual Analogue Scale (VAS). The patient will be asked to rate her pain on a 0–10 scale, where 0 indicates no pain and 10 indicates the worst imaginable pain. The VAS score will be recorded by a trained outcome assessor who is blinded to the study group allocation.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: Participants in this group will receive ultrasound-guided bilateral transversus abdominis plane block at the end of elective cesarean section under general anesthesia. The block will be performed using 40 mL of 0.25% bupivacaine, 20 mL on each side, plus dexmedetomidine 1 µg/kg as an adjuvant. The intervention will be administered as a single-dose bilateral block.

Category

Treatment - Drugs

2

Description

Control group: Participants in this group will receive ultrasound-guided bilateral transversus abdominis plane block at the end of elective cesarean section under general anesthesia. The block will be performed using 40 mL of 0.25% bupivacaine, 20 mL on each side, plus fentanyl 1 µg/kg as an active comparator. The intervention will be administered as a single-dose bilateral block.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
labbafi nejad hospital
Full name of responsible person
Mina Vishteh
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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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Shahid Chamran Highway- Evin- next to Taleghani Hospital- Medical School- third floor
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mina Vishteh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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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
Deidentified Individual Participant Data for the TAP Block Trial in Elective Cesarean Section
When the data will become available and for how long
After data collection completion
To whom data/document is available
Other researchers
Under which criteria data/document could be used
belonging to academic institution
From where data/document is obtainable
researcher's personal email minavishteh62@sbmu.ac.ir
What processes are involved for a request to access data/document
requesting by email
Comments