Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Studying the effects of intrathecal fentanyl on maternal hemodynamic changes and neonatal Apgar in elective cesarean sections

Protocol summary

Study aim
Determining the Effects of Intrathecal Fentanyl on Maternal Hemodynamic Changes and Neonatal Apgar Scores in Elective Cesarean Sections

Design
This study is a phase III randomized, double-blind, controlled clinical trial with parallel groups conducted on 100 patients. Participants will be allocated to the study groups using block randomization based on computer-generated random numbers produced by Random Allocation software.

Settings and conduct
This is a randomized double-blind clinical trial conducted at Kosar Hospital in Urmia. Candidates for elective cesarean section are allocated to intrathecal fentanyl and control groups. Spinal anesthesia is performed according to protocol, and maternal hemodynamic changes and neonatal Apgar scores are recorded. Both patients and outcome assessors are blinded, and the medications are prepared by an independent anesthesiologist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Gestational age of 37–40 weeks, singleton pregnancy, ASA physical status I or II, and provision of informed consent. Exclusion criteria: Presence of maternal conditions such as preeclampsia, severe cardiovascular, hepatic, or renal diseases; known hypersensitivity to fentanyl or local anesthetics; contraindications to spinal anesthesia (e.g., coagulation disorders or infection at the injection site); emergency delivery or fetal distress; morbid obesity (BMI > 40); and severe hemorrhage.

Intervention groups
Patients in the intervention group (intrathecal fentanyl group) will receive a solution containing 0.5% hyperbaric bupivacaine (10–12 mg) combined with 25 µg of fentanyl (0.5 mL). Patients in the control group will receive only a solution containing 0.5% hyperbaric bupivacaine (10–12 mg).

Main outcome variables
Effect of Intrathecal Fentanyl on Maternal Hemodynamic Changes and Neonatal Apgar Scores

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20260425069157N3**
Registration date: **2026-05-11, 1405/02/21**
Registration timing: **prospective**

Last update: **2026-05-11, 1405/02/21**
Update count: **0**

Registration date
2026-05-11, 1405/02/21

Registrant information
Name
Roghayea Neisari
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Iran (Islamic Republic of)
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Recruitment status
recruiting
Funding source

Expected recruitment start date
2026-05-22, 1405/03/01
Expected recruitment end date
2027-03-20, 1405/12/29
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effects of intrathecal fentanyl on maternal hemodynamic changes and neonatal Apgar in elective cesarean sections

Public title

Evaluation of the Effect of Adding Fentanyl to Cesarean Section Anesthesia on Maternal and Neonatal Outcomes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Gestational age of 37 to 40 weeks Singleton pregnancy ASA class I or II Informed consent to participate in the study

Exclusion criteria:

Presence of maternal diseases such as preeclampsia Severe cardiovascular diseases Hepatic or renal diseases Known hypersensitivity to fentanyl or local anesthetic drugs Presence of contraindications to spinal anesthesia (such as coagulation disorders or infection at the injection site) Emergency delivery or fetal distress Morbid obesity (BMI > 40) and cases with severe bleeding

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

One hundred patients who are candidates for elective cesarean section will be randomly allocated into intervention and control groups using block randomization based on computer-generated numbers created by Random Allocation software. Patients in the intervention group (intrathecal fentanyl group) will receive a solution containing 0.5% hyperbaric bupivacaine (10–12 mg) plus 25 µg fentanyl (0.5 mL). Patients in the control group will receive only a solution containing 0.5% hyperbaric bupivacaine (10–12 mg).

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be conducted in a double-blind manner; therefore, the medications will be prepared and administered by an anesthesiologist who is not involved in outcome assessment. Consequently, both the patients and the outcome assessor will be blinded to the group allocation (intervention or control).

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Imam Khomeini Hospital

Street address

Imam Khomeini University Hospital., Ershad Ave., Modarres Blvd., Urmia., Iran

City

Urmia

Province

West Azarbaijan

Postal code

5715781351

Approval date

2026-01-23, 1404/11/03

Ethics committee reference number

IR.UMSU.HIMAM.REC.1404.113

Health conditions studied

1

Description of health condition studied

Elective Cesarean Section, Spinal Anesthesia in Cesarean Section

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

Maternal hemodynamic changes, including systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial pressure (MAP), and heart rate (HR).

Timepoint

Before spinal anesthesia (baseline) and at 1, 3, 5, 10, and 15 minutes after spinal anesthesia.

Method of measurement

Hemodynamic parameters are measured and recorded using standard anesthesia monitoring equipment, including a non-invasive blood pressure monitor and ECG.

Secondary outcomes

1

Description
Neonatal Apgar score at 1 and 5 minutes after birth
Timepoint
At 1 minute and 5 minutes after birth.
Method of measurement
Apgar score is assessed by the neonatal team based on the five standard components: heart rate, respiratory effort, muscle tone, reflex irritability, and skin color.

Intervention groups

1

Description
Intervention group: Patients in the intervention group (intrathecal fentanyl group) will receive a solution containing 10–12 mg of 0.5% hyperbaric bupivacaine combined with 25 micrograms of fentanyl (0.5 mL).
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group will receive only a solution containing 10–12 mg of 0.5% hyperbaric bupivacaine
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Kowsar Hospital
Full name of responsible person
Dr. Roghayea Neisari
Street address
Kosar Comprehensive Women's Educational and Medical Center., Hasani Street., Urmia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
Street address
Urmia University of Medical Sciences., Emergency Alley., Resalat Boulevard., Urmia
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Web page address
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Roghayea Neisari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Kosar Comprehensive Women's Educational and Medical Center., Hasani Street., Urmia
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available