

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

nisari.r@umsu.ac.ir

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. Roghaye 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. Roghaye Neisari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

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Person responsible for scientific inquiries

Contact

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Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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