

# 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

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5715859497

##### Phone

+98 44 3346 0998

##### Fax

+98 44 3346 5079

##### Email

nisari.r@umsu.ac.ir

##### Web page address

<https://kosar.umsu.ac.ir>

## 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

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5718748983

##### Phone

+98 44 3237 5907

##### Email

sabergholizadeh@yahoo.com

##### Web page address

<http://umsu.ac.ir>

#### 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

Kosar Comprehensive Women's Educational and Medical Center., Hasani Street., Urmia

##### City

Urmia

##### Province

West Azarbaijan

**Postal code**

5718748983

**Phone**

+98 44 3346 0998

**Fax**

+98 44 3346 5079

**Email**

nisari.r@umsu.ac.ir

**Web page address**

<https://kosar.umsu.ac.ir>

## Person responsible for scientific 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

**Street address**

Kosar Comprehensive Women's Educational and Medical Center., Hasani Street., Urmia

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715859497

**Phone**

+98 44 3346 0998

**Fax**

+98 44 3346 5079

**Email**

nisari.r@umsu.ac.ir

**Web page address**

<https://kosar.umsu.ac.ir>

## Person responsible for updating data

**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

**Street address**

Kosar Comprehensive Women's Educational and Medical Center., Hasani Street., Urmia

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5715859497

**Phone**

+98 44 3346 0998

**Fax**

+98 44 3346 5079

**Email**

nisari.r@umsu.ac.ir

**Web page address**

<https://kosar.umsu.ac.ir>

## 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