

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Investigation of the intrathecal fentanyl effect on post spinal anesthesia headache in patients undergoing elective cesarean section

#### Protocol summary

##### Study aim

Investigation of the intrathecal fentanyl effect on post spinal anesthesia headache in patients undergoing elective cesarean section

##### Design

Double-blinded randomized clinical trial with block randomization, two parallel groups on 56 patients, phase III

##### Settings and conduct

Women between aged 15 and 35 years undergoing elective cesarean section under spinal anesthesia in Urmia Mahzad Hospital were included. In intervention group the spinal anesthesia will be performed using hyperbaric bupivacaine 0.5% (2.5 ml) and 25 micrograms of fentanyl (0.5 ml) and in the control group spinal anesthesia will be performed using only hyperbaric bupivacaine 0.5 % (2.5 ml). The patient and the person who will be assessed the outcomes (anesthesia assistant) will be blind about the intervention or control groups (Double-blinded).

##### Participants/Inclusion and exclusion criteria

In this study, 56 patients undergoing elective cesarean section under spinal anesthesia with aged 15 to 35 years will be included. The exclusion criteria are Any contraindication for spinal anesthesia; A history of migraine or chronic headache ; Mental diseases; Neurological diseases; Epilepsy; Coagulation disorders; Drug abusers; and Eclampsia and preeclampsia during pregnancy.

##### Intervention groups

In intervention group the spinal anesthesia will be performed using hyperbaric bupivacaine 0.5% (2.5 ml) and 25 micrograms of fentanyl (0.5 ml) and in the control group spinal anesthesia will be performed using only hyperbaric bupivacaine 0.5 % (2.5 ml).

##### Main outcome variables

Frequency and severity of headache

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170515033986N3**

Registration date: **2022-01-30, 1400/11/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-01-30, 1400/11/10**

Update count: **0**

##### Registration date

2022-01-30, 1400/11/10

##### Registrant information

##### Name

Nazli Karami

##### Name of organization / entity

Urmia University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3346 9932

##### Email address

karami.n@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-11-22, 1400/09/01

##### Expected recruitment end date

2022-03-20, 1400/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Investigation of the intrathecal fentanyl effect on post spinal anesthesia headache in patients undergoing elective cesarean section

## Public title

The effect of fentanyl on headache after cesarean section

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Women undergoing elective cesarean section under spinal anesthesia Women aged 15 to 35 years Patients with class ASA I and ASA II

### Exclusion criteria:

Any contraindication for spinal anesthesia A history of migraine or chronic headache Mental diseases Neurological diseases Epilepsy Coagulation disorders Drug abusers Eclampsia and preeclampsia during pregnancy

## Age

From **15 years** old to **35 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor

## Sample size

Target sample size: **56**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients will be divided into intervention and control groups using block randomization based on generated numbers by random allocation software.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Current study is a double blind study. The patient and the person who will be assessed the outcomes (anesthesia assistant) will be blind about the intervention or control groups. therefore, the drugs will be prepared and coded by another anesthesiologist or anesthesia assistant, and the spinal anesthesia will be performed by anesthesia assistant (principal investigator).

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

##### Street address

Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

#### Approval date

2021-11-01, 1400/08/10

#### Ethics committee reference number

IR.UMSU.REC.1400.286

## Health conditions studied

### 1

#### Description of health condition studied

Headache after cesarean section

#### ICD-10 code

G44

#### ICD-10 code description

Other headache syndromes

## Primary outcomes

### 1

#### Description

Frequency of headaches

#### Timepoint

In recovery, 6, 12 and 24 hours after surgery

#### Method of measurement

self-reporting

### 2

#### Description

The severity of the headache

#### Timepoint

In recovery, 6, 12 and 24 hours after surgery

#### Method of measurement

Verbal Rating Scale (VRS)

## Secondary outcomes

### 1

#### Description

Mean arterial blood pressure

#### Timepoint

In recovery, 6, 12 and 24 hours after surgery

## Method of measurement

Monitoring

## 2

### Description

Heart rate

### Timepoint

In recovery, 6, 12 and 24 hours after surgery

### Method of measurement

Monitoring

## Intervention groups

## 1

### Description

Intervention group: The spinal anesthesia will be performed using hyperbaric bupivacaine 0.5% (2.5 ml) and 25 micrograms of fentanyl (0.5 ml). Fentanyl is a product of Caspian Pharmaceutical Company. Hyperbaric bupivacaine 0.5% is a product of the French pharmaceutical company, MYLAN S.A.S. The drugs are injected as a single dose.

### Category

Treatment - Drugs

## 2

### Description

Control group: The spinal anesthesia will be performed only using hyperbaric bupivacaine 0.5% (2.5 ml). No opioid will be used intrathecally. This drug is a product of the French pharmaceutical company, MYLAN S.A.S. The drug is injected as a single dose.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Mahzad hospital

#### Full name of responsible person

Dr. Nazli Karami

#### Street address

Mahzad hospital; Hassani Ave; Urmia; Iran

#### City

Urmia

#### Province

West Azarbaijan

#### Postal code

57157-81351

#### Phone

+98 44 3198 8293

#### Email

karami.n@umsu.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Oroumia University of Medical Sciences

#### Full name of responsible person

Dr. Iraj Mohebbi

#### Street address

Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.

#### City

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#### Province

West Azarbaijan

#### Postal code

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#### Phone

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#### Email

mohebbi.i@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. Nazli Karami

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Anesthesiology

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Mahzad hospital, Hassani Ave., Urmia, Iran.

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Oroumia University of Medical Sciences  
**Full name of responsible person**

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**Position**  
Associate professor  
**Latest degree**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

There is no more information

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available