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-blined).

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 Siences

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, Jahad 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
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 44 3222 2010
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
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

Person responsible for scientific 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
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

Person responsible for updating data

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
Street address
Mahzad hospital; Gassani Ave; Urmia; Iran.
City
Urmia
Province
West Azarbaijan
Postal code
57157-81351
Phone
+98 44 3198 8293
Email
karami.n@umsu.ac.ir

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