Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparison of sedative dosage of Propofol and Dexamethasone on post-dural puncture headache after spinal anesthesia in women candidates for elective caesarean section

Protocol summary

Study aim
Comparison of sedative dosage of Propofol and Dexamethasone on post-dural puncture headache after spinal anesthesia in women candidates for elective caesarean section

Design
Randomized, double-blind, active controlled, parallel group, phase 3 clinical trial conducted on 150 patients. Randomization was performed using Random Allocation Software.

Settings and conduct
This is a Randomized, Double-Blind Clinical Trial aiming to compare the efficacy of Propofol and Dexamethasone on Post-Dural Puncture Headache (PDPH) following spinal anesthesia. 150 pregnant women scheduled for elective Cesarean section at Kowsar Hospital in Urmia will be randomly divided into two parallel groups (Propofol or Dexamethasone). For blinding purposes, medications are prepared in coded syringes by a person not involved in patient management, keeping both the patient and the assessor blinded to the drug type.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Pregnant women aged between 18 and 45 years; ASA physical status I or II (American Society of Anesthesiologists classification); Candidates for elective Cesarean section Exclusion Criteria: High-risk or induced pregnancy; Presence of uncontrolled chronic diseases (e.g., thyroid diseases, type I and II diabetes, hypertension, and cardiovascular disease); History of chronic headache, such as migraine; History of substance or corticosteroid use; Fever exceeding 38 degrees; Contraindications to spinal anesthesia

Intervention groups
Intervention group 1 (Propofol): Receiving Propofol infusion at a dose of 30 micrograms/kilograms/minute via infusion pump, immediately after neonate delivery. Intervention group 2 (Dexamethasone): Receiving 8 milligrams Dexamethasone intravenously, immediately after neonate delivery.

Main outcome variables
Headache score based on Visual Analog Scale.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20251010067579N1**
Registration date: **2025-12-09, 1404/09/18**
Registration timing: **prospective**

Last update: **2025-12-09, 1404/09/18**
Update count: **0**

Registration date
2025-12-09, 1404/09/18

Registrant information

Name
Aiden Kharazi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3329 1466

Email address
aiden.kharazi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-12-22, 1404/10/01

Expected recruitment end date
2026-02-19, 1404/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of sedative dosage of Propofol and Dexamethasone on post-dural puncture headache after spinal anesthesia in women candidates for elective caesarean section

Public title

comparison of sedative dosage of Propofol and Dexamethasone on post-dural puncture headache in women undergoing elective caesarean section

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

American Society of Anesthesiologists Physical status Classification I or II (ASA I or II status). Candidates for elective cesarean section surgery. Pregnant women between 18 to 45 years of age. Provision of written informed consent to participate in the study. Absence of absolute contraindication to spinal anesthesia.

Exclusion criteria:

High-risk or induced pregnancy Obesity (Body Mass Index or BMI greater than 38kg/m2) Presence of Thyroid disorders Presence of Type I or II Diabetes mellitus History of drug abuse or corticosteroid use Presence of Chronic or uncontrolled medical conditions Hypertension and Cardiovascular disease Fever exceeding 38 degrees Celsius History of Chronis headaches (e.g., Migraine) Absolute contraindication of spinal anesthesia Need for any change in anesthesia technique Occurrence of hemorrhage requiring blood transfusion Allergy to the study medications (Propofol or Dexamethasone)

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Use of Random allocation software

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be conducted as a double-blind randomized clinical trial. This means that the participants (pregnant women undergoing elective Cesarean section) and the study investigator/outcome assessor (who collects the outcome data) will be kept unaware of the type of drug administered to the patient. To ensure blinding, the study drugs (Propofol and Dexamethasone) will be prepared by an anesthesiologist who is not involved in the patient's anesthesia or post-operative management. The drugs will be prepared in identical volume coded syringes. These syringes will be coded so that neither the patient nor the investigator collecting the data (e.g., headache score via VAS) will be able to identify which treatment group (Group D or Group P) the patient belongs to. Furthermore, the data analyst may also remain blinded until the final data analysis is complete to prevent bias in result interpretation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Imam Khomeini Educational and Medical Center, Urmia University of Medic

Street address

Emam Khomeini University Hospital, Ershad Ave, Modarres Blvd, Urmia

City

Urmia

Province

West Azarbaijan

Postal code

5715789397

Approval date

2025-07-30, 1404/05/08

Ethics committee reference number

IR.UMSU.HIMAM.REC.1404.041

Health conditions studied

1

Description of health condition studied

post-dural puncture headache after spinal anesthesia

ICD-10 code

O89.4

ICD-10 code description

Spinal and epidural anesthesia-induced headache during the puerperium

Primary outcomes

1

Description
Headache score
Timepoint
1, 2, 24 hours and 2nd to 7th days after surgery
Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Systolic Blood Pressure
Timepoint
1, 2, 24 hours after surgery
Method of measurement
Millimeter of mercury (sphygmomanometer)

2

Description
Diastolic Blood Pressure
Timepoint
1, 2, 24 hours after surgery
Method of measurement
Millimeter of mercury (sphygmomanometer)

3

Description
Mean Arterial Pressure
Timepoint
1, 2, 24 hours after surgery
Method of measurement
Millimeter of mercury (calculated via specific formula)

4

Description
Heart rate
Timepoint
1, 2, 24 hours after surgery
Method of measurement
Beats per minute (Pulse oximetry)

5

Description
Peripheral Oxygen Saturation
Timepoint
1, 2, 24 hours after surgery
Method of measurement
Percentage (Pulse oximetry)

Intervention groups

1

Description
Intervention group: Propofol
Category
Treatment - Drugs

2

Description
Intervention group: Dexamethasone
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Women's Comprehensive Educational and Therapeutic Center
Full name of responsible person
Aiden Kharazi
Street address
Hasani St, Kowsar Women's Comprehensive Educational and Therapeutic Center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Aiden Kharazi
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4th floor, Taban tower, Homafar St, Valiasr
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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

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Aiden Kharazi

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

De-identified Individual Participant Data (IPD) including demographic variables, headache intensity scores based on VAS criteria, and hemodynamic parameters (SBP, DBP, MAP, HR, SPO2) along with the study protocol will be available for sharing.

When the data will become available and for how long

Access to data will be available 6 months after the publication of the final results and will continue for 2

years.

To whom data/document is available

Researchers employed in academic and scientific institutions who intend to conduct meta-analysis or systematic reviews on clinical trial data in the field of anesthesia management and postoperative pain.

Under which criteria data/document could be used

Data is usable solely for secondary statistical analysis and inclusion in meta-analysis studies. Use of data is conditional upon citing the original source and adhering to publication ethics.

From where data/document is obtainable

Dr. Nasim Shamsa (Assistant Professor of Anesthesiology, Urmia University of Medical Sciences). Aiden Kharazi Email: aiden.kharazi@gmail.com

What processes are involved for a request to access data/document

Applicants must send their written request, including the research proposal and analysis objectives, to the corresponding author's email address. Upon scientific and ethical review by the principal investigators, data will be shared as an encrypted file.

Comments