Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

comparison of The effectiveness of intravenous dexamethasone with intravenous ondansetron in preventingheadache after spinal anesthesia in cesarean scetion

Protocol summary

Study aim

Comparison of the Efficacy of Intravenous Dexamethasone versus Intravenous Ondansetron in Preventing Post-Dural Puncture Headache Following Spinal Anesthesia

Design

This study is a randomized, double-blind, three-arm, controlled clinical trial. Participants are recruited using convenience sampling and are then randomly allocated to the three study groups using simple randomization. The final sample size is 120 participants, with 40 participants in each group.

Settings and conduct

The study will be conducted among pregnant women undergoing cesarean section under spinal anesthesia. Participants will be recruited through convenience sampling, and allocation to the study groups will be performed using simple randomization. Data will be collected in the clinical setting using a researcher-made checklist. Study setting and time: Hajar Hospital, Shahrekord, Iran, in 2025 (1404 in the Iranian calendar).

Participants/Inclusion and exclusion criteria

Patients aged 18–50 years Absence of concomitant infectious diseases. Absence of moderate-to-severe chronic headache within 24 hours prior to anesthesia. No administration of analgesic drugs or medications with analgesic properties within 24 hours prior to anesthesia. Absence of preeclampsia or gestational diabetes mellitus. No known history of hypersensitivity or allergy to dexamethasone or ondansetron.

Intervention groups

Group A Receives 4 mg intravenous dexamethasone in a volume of 4 mL. Group B Receives 8 mg intravenous ondansetron in a volume of 4 mL. Group C Receives 4 mL intravenous distilled water (placebo

Main outcome variables

he main outcome variables assessed in the study include: Incidence of post-dural puncture headache (PDPH) at 6, 12, 24, 48, and 72 hours after surgery. Severity of PDPH at the same time points. Incidence of surgical complications, such as wound infection and bleeding.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260907070952N1**
Registration date: **2026-09-14, 1405/06/23**
Registration timing: **prospective**

Last update: **2026-09-14, 1405/06/23**
Update count: **0**

Registration date

2026-09-14, 1405/06/23

Registrant information

Name

Maryam Sadeghi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

sadeghi150@yahoo.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

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
comparison of The effectiveness of intravenous dexamethasone with intravenous ondansetron in preventingheadache after spinal anesthesia in cesarean scetion

Public title
Comparison of the Effects of Dexamethasone and Ondansetron on Preventing Headache After Spinal Anesthesia in Women Undergoing Cesarean Section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
The patient's willingness to participate in the study and completion of the informed consent form. Patients who are candidates for elective cesarean section under spinal anesthesia Patients aged 18–50 years Absence of concurrent infectious disease Absence of moderate-to-severe chronic headache within 24 hours before anesthesia. No administration of analgesics or medications with analgesic properties within 24 hours before anesthesia. Absence of substance abuse. Absence of preeclampsia or gestational diabetes mellitus. No known history of drug hypersensitivity to dexamethasone or ondansetron. American Society of Anesthesiologists (ASA) physical status classification I–II No use of systemic corticosteroids during the preceding two weeks. No known coagulation disorders (platelet count <100,000/μL, INR ≥1.6, or prolonged PT). No use of anticoagulant medications such as low-molecular-weight heparin (LMWH) within 12 hours before spinal anesthesia, or other antiplatelet medications. Absence of spinal abnormalities (such as severe scoliosis or lumbar tumors) that may interfere with spinal anesthesia Adequate cooperation to complete the questionnaires and assess pain intensity using the Visual Analog Scale (VAS Normal electrocardiogram (ECG)
Exclusion criteria:
Any change in the anesthesia technique Occurrence of surgical or anesthetic complications Prolongation of the surgical procedure to more than 3 hours The patient's desire to withdraw from the study A history of diabetes mellitus
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
1-2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
This study is a double-blind randomized clinical trial in which neither the patients nor the researcher is aware of the medication administered. Eligible patients will be selected using convenience sampling. After obtaining informed consent, the participants will be randomly allocated using Random Allocation Software into three groups of 40 patients each: Group A (dexamethasone), Group B (ondansetron), and the control group (distilled water).
Blinding (investigator's opinion)
Double blinded
Blinding description
This study will be conducted using a double-blind design, such that neither the patients nor the researcher/outcome assessor will be aware of the treatment allocation. The study medications, including dexamethasone, ondansetron, and distilled water, will be prepared in equal final volumes and placed in identical coded syringes by an independent individual who is not involved in the assessment or data collection. The coded syringes will then be provided to the study investigator, and the treatment allocation codes will remain concealed until completion of data collection and analysis. In case of a medical emergency requiring knowledge of the administered treatment, the blinding code may be broken for the respective patien
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahrekord University of Medical Sciences
Street address
رحمتیه دانشگاه علوم پزشکی شهرکرد دانشکده پزشکی
City
شهرکرد
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Approval date
2026-08-31, 1405/06/09
Ethics committee reference number
IR.SKUMS.MED.REC.1405.141

Health conditions studied

1

Description of health condition studied
Prevention of Post-Dural Puncture Headache Following Spinal Anesthesia
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Post-Dural Puncture Headache Following Spinal Anesthesia
Timepoint
6, 12, 24, 48, and 72 hours after spinal anesthesia
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Dexamethasone at a dose of 4 mg is diluted with distilled water to a total volume of 4 mL and administered intravenously immediately after delivery and umbilical cord clamping.
Category
Prevention

2

Description
Intervention group: Ondansetron at a dose of 8 mg is diluted to a total volume of 4 mL and administered intravenously immediately after delivery and umbilical cord clamping.
Category
Prevention

3

Description
Control group: They receive 4 mL of distilled water, which is administered intravenously immediately after delivery and umbilical cord clamping.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Hajar Hospital
Full name of responsible person
maryam sadeghi
Street address
Kashani Boulevard, Parastar Street, Central Administration of Shahrekord University of Medical Sciences, Hajar Hospital, Shahrekord
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Ali Hassanpour
Street address
Kashani Boulevard, Parastar Street, Central Administration of Shahrekord University of Medical
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Maryam Sadeghi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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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