Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

A Comparison of the Efficacy of Metoclopramide and Ondansetron in Reducing Nausea and Vomiting during Spinal Anesthesia for Elective Cesarean Section

Protocol summary

Study aim

Determining the Effectiveness of Metoclopramide and Ondansetron in Reducing Nausea and Vomiting During Spinal Anesthesia in Elective Cesarean Section

Design

This study is a randomized, double-blind, parallel-group, phase 3 clinical trial. One hundred elective cesarean patients will be enrolled and allocated into two groups using the Excel RAND function. The intervention is administered 5 minutes before spinal anesthesia, and both participants and outcome assessors are blinded to group allocation.

Settings and conduct

This randomized double-blind trial at Kosar Hospital compares metoclopramide and ondansetron for reducing nausea and vomiting during spinal anesthesia. Patients receive one of the drugs 5 minutes before anesthesia. Spinal anesthesia is standardized. Both patients and the outcome assessor are blinded, with drugs prepared in identical syringes by an independent provider.

Participants/Inclusion and exclusion criteria

Inclusion criteria: women aged 18–40 years, informed consent, singleton pregnancy undergoing elective cesarean section, and ASA physical status I–II. Exclusion criteria: withdrawal of consent, known hypersensitivity to metoclopramide or ondansetron (or their components), and occurrence of drug-related adverse effects.

Intervention groups

The intervention includes two groups: Metoclopramide group (M): Patients receive 10 mg of intravenous metoclopramide. Ondansetron group (O): Patients receive 4 mg of intravenous ondansetron. In both groups, the study drug will be diluted with normal saline to an equal volume (5 mL) and administered as a slow intravenous injection 5 minutes before spinal anesthesia. The timing, injection volume, administration rate, anesthesia protocol, and pre-anesthetic care will be identical in both groups. The selected doses and timing are based on previous studies and commonly used protocols.

Main outcome variables

nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260425069157N1**
Registration date: **2026-04-28, 1405/02/08**
Registration timing: **prospective**

Last update: **2026-04-28, 1405/02/08**
Update count: **0**

Registration date

2026-04-28, 1405/02/08

Registrant information

Name

Roghayea Neisari

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3346 9931

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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
A Comparison of the Efficacy of Metoclopramide and Ondansetron in Reducing Nausea and Vomiting during Spinal Anesthesia for Elective Cesarean Section

Public title
Effects of Metoclopramide and Ondansetron on Post-Cesarean Nausea and Vomiting
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18–40 years Willingness to participate and providing informed consent Singleton pregnancy undergoing elective cesarean section ASA physical status class I–II
Exclusion criteria:
Withdrawal of consent at any stage of the study Known hypersensitivity to metoclopramide, ondansetron, or any component of their formulations Development of drug-related adverse effects
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be randomized using block randomization with fixed block sizes of four. The random allocation sequence will be generated by computer software, and within each block, patients will be randomly assigned to either Group A or Group B. To prevent selection bias, allocation concealment will be ensured using the SNOSE method (Sequentially Numbered, Opaque, Sealed Envelopes). The random sequence will be placed inside opaque, sequentially numbered, sealed envelopes, which will be opened only after participant enrollment.
Blinding (investigator's opinion)
Double blinded
Blinding description
To maintain blinding, both medications (metoclopramide and ondansetron) are clear, colorless injectable solutions and are indistinguishable in appearance, volume, and method of administration. The medications will be prepared by an independent person in identical unlabelled syringes and coded as A/B. Therefore, both participants and outcome assessors will remain unaware of the allocated intervention, ensuring effective blinding at both participant and assessor levels.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences., Emergency Alley., Resalat Boulevard., Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5715781351
Approval date
2026-02-18, 1404/11/29
Ethics committee reference number
IR.UMSU.REC.1404.522

Health conditions studied

1

Description of health condition studied
Elective cesarean section
ICD-10 code
O82
ICD-10 code description
Encounter for cesarean delivery without indication

Primary outcomes

1

Description
Incidence and frequency of nausea and vomiting following the intervention.
Timepoint
0–1 hour after intervention,1–2 hours after intervention,2–4 hours after intervention,4–6 hours after intervention
Method of measurement
The incidence of nausea and vomiting will be recorded as dichotomous variables (Yes/No). In addition, the frequency (number of episodes) of nausea and vomiting will be documented during the following postoperative

time intervals:

Secondary outcomes

empty

Intervention groups

1

Description
Ten milligrams of injectable metoclopramide (10 mg/2 mL ampoule, Sina Darou Pharmaceutical Co., Iran) diluted with normal saline to a final volume of 5 mL will be administered intravenously over 30–60 seconds, 5 minutes before spinal anesthesia. The final volume, timing, injection rate, and all anesthesia-related conditions will be identical in both groups.
Category
Treatment - Surgery

2

Description
Four milligrams of injectable ondansetron (4 mg/2 mL ampoule, Actoverco Pharmaceutical Co., Iran) diluted with normal saline to a final volume of 5 mL will be administered intravenously over 30–60 seconds, 5 minutes before spinal anesthesia. All injection conditions and anesthesia protocols will match those of the metoclopramide group.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Comprehensive Women’s Educational and Medical Center.,
Full name of responsible person
Dr. Roghayea Neisari
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Kosar Comprehensive Women’s Educational and Medical Center., Hasani Street., Urmia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
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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
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. Roghayea Neisari
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