# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

12 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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**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**
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**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
**Street address**
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
**Full name of responsible person**
Dr. Saber Gholizadeh
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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 scientific inquiries

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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