Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effect of Non-Pharmacological Interventions Versus a Combination of Ondansetron and Pethidine on Shivering, Nausea, and Vomiting after Spinal Anesthesia for Cesarean Section

Protocol summary

Study aim
Comparison of the Impact of Non-pharmacological interventions vs. a combination of ondansetron & Pethidine on Shivering & Nausea & Vomiting after spinal Anesthesia for cesarean section

Design
Randomization will be performed using sealed opaque envelopes with variable block randomization, and outcome assessors will be blinded to group allocation.

Settings and conduct
This study will be conducted at a teaching/specialized hospital affiliated with Ahvaz Jundishapur University of Medical Sciences (with full obstetrics and anesthesia facilities).

Participants/Inclusion and exclusion criteria
Scheduled for elective cesarean section under spinal anesthesia American Society of Anesthesiologists (ASA) physical status I or II Full-term pregnancy (gestational age ≥37 weeks) Body Mass Index (BMI) between 18 and 35 kg/m² Willing to participate and provide written informed consent Patient refusal to participate or withdrawal of consent at any time during the study Emergency cesarean sections Known hypersensitivity or allergy to ondansetron, pethidine, or local anesthetic agents Contraindications to spinal anesthesia (coagulopathy, local infection at puncture site, increased intracranial pressure, severe hypovolemia) Patients with severe cardiovascular, respiratory, hepatic, or renal disorders Pre-existing neurological disorders Baseline hypothermia (core body temperature <35°C) or fever (>38°C) History of chronic pain or regular opioid use Patients on medications affecting thermoregulation or antiemetic medications

Intervention groups
Participants will be randomly allocated to one of two groups: (1) the non-pharmacological interventions group or (2) the pharmacological interventions group (ondansetron + pethidine combination)

Main outcome variables
Incidence and Severity of Shivering and Nausea

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260210068821N1**
Registration date: **2026-02-18, 1404/11/29**
Registration timing: **prospective**

Last update: **2026-02-18, 1404/11/29**
Update count: **0**

Registration date
2026-02-18, 1404/11/29

Registrant information

Name
ALI KHALAFI

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 916 335 9407

Email address
khalafi.a2006@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-04-08, 1405/01/19

Expected recruitment end date
2026-05-19, 1405/02/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effect of Non-Pharmacological Interventions Versus a Combination of Ondansetron and Pethidine on Shivering, Nausea, and Vomiting after Spinal Anesthesia for Cesarean Section

Public title
Non-Drug Methods vs. Drug Combination for Shivering and Nausea after Spinal Anesthesia in Cesarean Section
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women aged 18 to 45 years candidates for elective cesarean section under spinal anesthesia ASA physical status class I or II gestational age ≥37 weeks provision of written informed consent
Exclusion criteria:
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
In the present study, participants will be allocated to the two intervention groups (non-pharmacological and pharmacological) using block randomization with variable block sizes (4 and 6) via sequentially numbered, sealed, opaque envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
This study will employ a single-blind design. In this design, participants (patients) will be aware of their group allocation due to the tangible nature of the interventions. However, outcome assessors and data analysts will remain blinded to group assignment until the completion of the primary analysis. The principal investigator responsible for administering the interventions and initial data recording will not be blinded due to the practical nature of the interventions.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Esfand
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Approval date
2026-02-13, 1404/11/24
Ethics committee reference number
IR.AJUMS.REC.1404.622

Health conditions studied

1

Description of health condition studied
Incidence and Severity of Shivering and Nausea in Cesarean Section
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Incidence of shivering, defined as the presence or absence (yes/no) of at least one episode of involuntary and observable shivering; severity of shivering, measured using the Wrench Shivering Grading Scale (0 to 3); and incidence of nausea, defined as patient-reported subjective feeling of the need to vomit (yes/no). All outcomes are assessed from the start of the intervention until 60 minutes (for shivering) and 6 hours (for nausea) after the completion of the cesarean section.
Timepoint
Shivering outcomes are monitored continuously up to 60 minutes postoperatively, and nausea is assessed at three time points: at the end of the surgery, and at 2 hours and 6 hours after surgery.
Method of measurement
check list

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: the pharmacological interventions group (ondansetron + pethidine combination).
Category
Treatment - Drugs

2

Description
Control group: the non-pharmacological interventions group
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hospital, Razi Hospital, and Taleghani Hospital
Full name of responsible person
ALI KHALAFI
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Sponsors / Funding sources

1

Sponsor
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Ahvaz 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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
ALI KHALAFI
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Anesthesiology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

De-identified individual participant data. This set includes all raw data collected per protocol: baseline demographics, primary outcomes (incidence and severity of shivering, incidence of nausea and vomiting), secondary outcomes (vital signs), and safety data. Data will be shared in a structured Excel or CSV file after removal of all direct identifiers (name, medical record number, phone number) and coding.

When the data will become available and for how long

Data will become publicly available 12 months after the publication of the primary study results in a peer-reviewed journal and will remain accessible for at least 5 years thereafter.

To whom data/document is available

Access is open to academic researchers and scientists affiliated with credible research or educational institutions, for the purpose of conducting valid scientific secondary analyses or meta-analyses.

Under which criteria data/document could be used

Data may only be used for non-commercial research purposes with proper citation of the original study. Requestors must submit a brief scientific analysis proposal (max 1 page) outlining the aims, methods, and intended outputs of the secondary analysis. Use for validation of findings or educational purposes is permitted.

From where data/document is obtainable

Requests should be submitted via email to the study's corresponding researcher: Title: Assistant/Associate Professor of Anesthesiology Affiliation: Ahvaz Jundishapur University of Medical Sciences

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

Upon receipt of a formal request and analysis proposal, the Study Data Access Committee will review the request for alignment with the stated purposes and conditions within 4 weeks and communicate its decision via email. If approved, data will be shared within 2 weeks after receiving a signed data use agreement.

Comments