

# 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  $\geq 37$  weeks) Body Mass Index (BMI) between 18 and 35 kg/m<sup>2</sup> 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  $< 35^{\circ}\text{C}$ ) or fever ( $> 38^{\circ}\text{C}$ ) 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  $\geq 37$  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

##### Street address

.

##### City

AHVAZ

##### Province

Khuzestan

##### Postal code

11111111

##### Phone

+98 916 335 9407

##### Email

khalafi.a2006@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Ahvaz University of Medical Sciences

##### Full name of responsible person

ALI KHALAFI

##### Street address

.Ahvaz, Golestan, Esfand Street, Jundishapur University of Medical Sciences, Faculty of Paramedical Sciences

##### City

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##### Province

Khuzestan

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khalafi.a2006@gmail.com

#### 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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Ahvaz, golestan

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## Person responsible for scientific 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

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
ALI KHALAFI  
**Position**  
Associate professor  
**Latest degree**  
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**Other areas of specialty/work**  
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**Province**  
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**Postal code**  
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**Email**  
khalafi.a2006@gmail.com

## 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