

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### A Comparison of the prophylactic effect of granisetron and meperidine on reducing shivering after elective cesarean under spinal anesthesia

#### Protocol summary

##### Study aim

A Comparison of the prophylactic effect of granisetron and meperidine on reducing shivering after elective cesarean under spinal anesthesia

##### Design

A double-blind, randomized clinical trial study with parallel groups and phases 3 on 100 patients. Randomization will be done with the block randomization method using Random allocation software.

##### Settings and conduct

This study will be conducted on elective cesarean patients under spinal anesthesia in Urmia Mahzad Hospital. This study will be a double-blind study and the patient and the researcher who will evaluate the outcomes will be blinded to the allocation of patients into groups.

##### Participants/Inclusion and exclusion criteria

In this study, 100 patients of 20 to 40 years under elective cesarean section with spinal anesthesia will be enrolled. Women with chronic diseases, hypertension, diabetes, psychological disorders, and surgeries longer than an hour will be excluded.

##### Intervention groups

In all patients, the spinal anesthesia will be performed using a standard 25 Quincke needle at L3-4 with hyperbaric 0.5 % bupivacaine 10 mg. Then, after the baby is born, patients will be injected with 0.4 mg/kg granisetron (group A) or 0.4 mg/kg meperidine (group B).

##### Main outcome variables

shivering

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170516033992N10**

Registration date: **2022-04-12, 1401/01/23**

Registration timing: **prospective**

Last update: **2022-04-12, 1401/01/23**

Update count: **0**

##### Registration date

2022-04-12, 1401/01/23

##### Registrant information

###### Name

**Name of organization / entity**

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 3222 2010

###### Email address

karami.t@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-05-22, 1401/03/01

##### Expected recruitment end date

2022-10-22, 1401/07/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A Comparison of the prophylactic effect of granisetron and meperidine on reducing shivering after elective cesarean under spinal anesthesia

##### Public title

The effect of granisetron and meperidine on shivering after elective cesarean

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Patients undergoing elective cesarean section with spinal anesthesia Age between 20 to 40 years Patients with physical status one and two according to the criteria of the American Anesthesia Association (ASA I, II) Women with full-term pregnancy (more than 37 weeks)

**Exclusion criteria:**

Chronic diseases Hypertension Diabetes Psychological disorders Drug allergy Cesarean section more than an hour

**Age**

From **20 years** old to **40 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be divided into two groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be selected. Patients will be allocated to groups based on generated numbers.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study will be conducted as a double-blind clinical trial. The patient and the researcher who will be evaluating the outcomes will be blind to the allocation of patients into granisetron or meperidine groups. Group names will be encoded with the letters A and B.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics Committee of Urmia University of Medical Sciences

**Street address**

Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran.

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5714783734

**Approval date**

2022-03-02, 1400/12/11

**Ethics committee reference number**

IR.UMSU.REC.1401.002

**Health conditions studied**

1

**Description of health condition studied**

Shivering after elective cesarean section with spinal anesthesia

**ICD-10 code**

JB22.0

**ICD-10 code description**

Delivery by elective caesarean section

**Primary outcomes**

1

**Description**

shivering

**Timepoint**

Every 5 minutes after surgery

**Method of measurement**

Clinical examination

**Secondary outcomes**

1

**Description**

Mean arterial pressure (MAP)

**Timepoint**

Before, during and every 5 minutes after surgery

**Method of measurement**

Monitoring

2

**Description**

Heart rate

**Timepoint**

Before, during and every 5 minutes after surgery

**Method of measurement**

Monitoring

3

**Description**

Percentage of arterial blood oxygen saturation

**Timepoint**

Before, during and every 5 minutes after surgery

**Method of measurement**

Monitoring

## Intervention groups

### 1

#### Description

Intervention group: The spinal anesthesia will be performed using a standard 25 Quincke needle at L3-4 with hyperbaric 0.5 % bupivacaine 10 mg. Then, after the baby is born, patients will be injected with 0.4 mg/kg granisetron (group A).

#### Category

Treatment - Other

### 2

#### Description

Intervention group: The spinal anesthesia will be performed using a standard 25 Quincke needle at L3-4 with hyperbaric 0.5 % bupivacaine 10 mg. Then, after the baby is born, patients will be injected with 0.4 mg/kg meperidine (group B).

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Urmia Mahzad hospital

##### Full name of responsible person

Dr. Tohid Karami

##### Street address

Hassani Ave, Mahzad hospital, Urmia,Iran.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5715859497

##### Phone

+98 44 3346 5079

##### Email

karami.t@umsu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Saber Gholizadeh

##### Street address

Urmia University of Medical Sciences, Resalat street, Jihad Blvd., Urmia, Iran.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

4

##### Phone

+98 44 3223 4897

##### Email

gholizadeh.s@umsu.ac.ir

##### 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. Tohid Karami

##### Position

Assistant professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Mahzad hospital, Hassani Ave, Urmia, Iran.

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##### Province

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Tohid Karami

##### Position

Assistant professor

##### Latest degree

Subspecialist

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Tohid Karami

**Position**

Assistant professor

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidentiality of patient information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The data will not be published individually and the results will be available as the published articles.

**When the data will become available and for how long**

After publishing the article

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

Not applicable

**From where data/document is obtainable**

Email address of the corresponding author

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

Email address: karami.t@umsu.ac.ir

**Comments**