

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.

City

Urmia

Province

West Azarbaijan

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5715859497

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+98 44 3346 5079

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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

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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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