

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Prophylactic effect of intravenous injection of Ondansetron versus placebo on shivering after spinal anesthesia in cesarean section: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the prophylactic effect of intravenous injection of Ondansetron versus placebo on shivering after spinal anesthesia in cesarean section

Design

This is a double-blind randomized clinical trial, phase II, in which 72 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with indication of cesarean section referring to the Fatemieh Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 35 years, Candidate for elective cesarean, Exclusion criteria: Sensitivity to Ondansetron, Heart disease, Liver or kidney disease, Body temperature above 38-degree centigrade, Body temperature below 36.5-degree centigrade, Need to transfusion, Length of surgery more than 180 minutes

Intervention groups

Intervention group: Intravenous Ondansetron (manufactured by Tehran Chemistry Pharmaceutical Co.) 2 ml (4 mg) single dose 0.5 hour before surgery Control group: Intravenous normal saline (manufactured by Tehran Chemistry Pharmaceutical Co.) 2 ml single dose 0.5 hour before surgery

Main outcome variables

Primary outcome: Observation of shivering, Secondary outcome: Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N362**

Registration date: **2020-07-27, 1399/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-29, 1399/05/08**

Update count: **1**

Registration date

2020-07-27, 1399/05/06

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-20, 1399/01/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Prophylactic effect of intravenous injection of Ondansetron versus placebo on shivering after spinal anesthesia in cesarean section: a double-blind randomized clinical trial

Public title

Prophylactic effect of intravenous injection of Ondansetron versus placebo on shivering after spinal anesthesia in cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 35 years, Candidate for elective cesarean,

Exclusion criteria:

Sensitivity to Ondansetron, Heart disease, Liver or kidney disease, Body temperature above 38 degree centigrade, Body temperature below 36.5 degree centigrade, Need to transfusion, Length of surgery more than 180 minutes

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs will be given in coded envelopes. The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2020-02-08, 1398/11/19

Ethics committee reference number

IR.UMSHA.REC.1398.998

Health conditions studied

1

Description of health condition studied

Cesarean

ICD-10 code

Z38.01

ICD-10 code description

Single liveborn infant, delivered by cesarean

Primary outcomes

1

Description

Observation of shivering

Timepoint

During surgery every 15 minutes and after surgery in the recovery unit every half an hour

Method of measurement

Using a standard checklist called Bedside Four Point Scale

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

After surgery in recovery unit every half an hour

Method of measurement

By taking history and physical examination

Intervention groups

1

Description

Intervention group: Intravenous Ondansetron
(manufactured by Tehran Chemistry Pharmaceutical Co.)
2 ml (4 mg) single dose 0.5 hour before surgery

Category

Treatment - Drugs

2

Description

Control group: Intravenous normal saline (manufactured
by Mashhad Samen Pharmaceutical Co.) 2 ml single dose
0.5 hour before surgery

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital in Hamadan city

Full name of responsible person

Maryam Malekfar

Street address

Fatemieh Hospital, Pasdaran Ave.

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+98 81 3828 3939

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Saeid Bashirian

Street address

Hamadan University of Medical Sciences, Shahid
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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Maryam Malekfar

Position

Medical Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Jalal Poorolajal

Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Hamadan

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