

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of the prophylactic effect of intravenous Propofol, Dexamethasone and Ondansetron on post operative nausea and vomiting in elective cesarean section under spinal anesthesia

Protocol summary

Study aim

Determining the prophylactic effect of Propofol, Dexamethasone and Ondansetron on post operative nausea and vomiting in elective cesarean section under spinal anesthesia

Design

In this double-blind clinical trial parallel study (phase 3), 120 pregnant women candidates for cesarean section undergoing spinal anesthesia were included. Patients were randomly divided into four groups using generated computer numbers. Patients were injected with 0.05 Mg/kg of Ondansetron in group 1, 0.1 Mg/kg of Dexamethasone in group 2, 0.2 Mg/kg of Propofol in group 3 and normal saline in group 4 (control group).

Settings and conduct

This study was performed on women undergoing elective cesarean section under spinal anesthesia admitted to Urmia Shahid Motehary.

Participants/Inclusion and exclusion criteria

In this double-blind clinical trial study, women in the age range of 15 to 35 years who were candidates for cesarean section were included. Women with gastrointestinal disorders, eclampsia and preeclampsia, a history of taking anti-depression drugs, a history of surgery, motion sickness and weight more than 100 kg were excluded.

Intervention groups

Participants were randomly divided into four groups: Patients were injected with 0.05 Mg/kg of Ondansetron in group 1, 0.1 Mg/kg of Dexamethasone in group 2, 0.2 Mg/kg of Propofol in group 3 and normal saline in group 4 (control group).

Main outcome variables

Nausea and vomiting after cesarean section

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170408033280N3**

Registration date: **2020-12-12, 1399/09/22**

Registration timing: **retrospective**

Last update: **2020-12-12, 1399/09/22**

Update count: **0**

Registration date

2020-12-12, 1399/09/22

Registrant information

Name

Ebrahim Hassani

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 44 3346 8967

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ehassani@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

2019-07-23, 1398/05/01

Actual recruitment end date

2020-01-20, 1398/10/30

Trial completion date

2020-01-20, 1398/10/30

Scientific title

Comparison of the prophylactic effect of intravenous Propofol, Dexamethasone and Ondansetron on post operative nausea and vomiting in elective cesarean section under spinal anesthesia

Public title

The effect of intravenous Propofol, Dexamethasone and Ondansetron in preventing nausea and vomiting after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women under cesarean section Age group 15-35 years old American Society of Anesthesiologists classification system I and II (ASA I and ASA II)

Exclusion criteria:

Having a history of anti depression drugs consumption Gastrointestinal disorders Motion sickness Weight >100 Kg Having a history of other surgeries Patients with preeclampsia and eclampsia during pregnancy Taking anti-nausea and vomiting medications 24 hours before cesarean section

Age

From **15 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into intervention and control groups using Random allocation computer software. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients allocated into four groups according computer generated numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was a double-blind clinical trial. participants and researcher were unaware about the patient belonged to the interventions or a control groups. The drugs were injected by an anesthesiologist (other than the lead researcher) who was unaware of the content of the study.

Placebo

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, Jahad Ave, Urmia, Iran.

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2019-06-19, 1398/03/29

Ethics committee reference number

IR.UMSU.REC.1398.085

Health conditions studied

1

Description of health condition studied

Nausea and vomiting after cesarean section

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea

Timepoint

Recovery and six hours after surgery

Method of measurement

Asking the patient

2

Description

Vomiting

Timepoint

Recovery and six hours after surgery

Method of measurement

Push out stomach contents from the mouth

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: group 1: Received 0.05 Mg/kg of Ondansetron from Kaspian-Farma company (Iran country) after the fetus leaves and umbilical cord clamp by the surgeon.

Category

Treatment - Drugs

2

Description

Intervention group: group 2: Received 0.1 Mg/kg of Dexamethasone from Shimi-Daru company (Iran country) after the fetus leaves and umbilical cord clamp by the surgeon.

Category

Treatment - Drugs

3

Description

Intervention group: group 3: Received 0.2 Mg/kg of Propofol from Tehran-Shimi company (Iran country) after the fetus leaves and umbilical cord clamp by the surgeon.

Category

Treatment - Drugs

4

Description

Control group: Normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia Motahari Hospital

Full name of responsible person

Dr. Ebrahim Hassani

Street address

Shahid Motahhari hospital; Kashani street, Urmia, Iran.

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ehassani@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebbi

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Urmia University of Medical Sciences; Resalat street; Jahad Blvd; Urmia; Iran.

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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

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. Ebrahim Hassani

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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

Yes - There is 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

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The results of the study will be published as an article.

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

As published article

From where data/document is obtainable

Corresponding author

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

by email address

Comments