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 Motahari.

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 II 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
Vomoting

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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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 updating data

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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