Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

A comparative study of the effects of Dexamethasone and Ondansetron on nausea and vomiting in cesarean section under spinal anesthesia by Bupivacaine (Marcaine)

Protocol summary

Study aim

Considering the importance of controlling and preventing postoperative nausea and vomiting, and the availability and affordability of Dexamethasone and Endonestrone, we decided to investigate their effects on reducing these complications

Design

A double-blind, randomized clinical trial without control group, With parallel groups

Settings and conduct

The study population include all patients who are referred to the operating room of the Asali charity Hospital for elective cesarean section. Sampling method: The method of selecting the samples is available and assigning them to the groups under study using stratified random blocks method.

Participants/Inclusion and exclusion criteria

inclusion criteria: Include all patients who have been referred for elective cesarean section; ASA class one and two; In fertility; Patients with normal, mild to moderate stress, anxiety and depression; and patients with bupivacaine 0.5% spinal anesthesia. exclusion creteria: Patients with gestational toxicity; History of motion sickness, history of meniere syndrome, migraine; BMI higher than 40; History and practice of post-implementation; Severe or severe stress, anxiety and depression; smoking and the use of opiate drugs; People who are not willing to cooperate; patients who have a 5% lidocaine spinal anesthetic; Patients receiving atropine during surgery.

Intervention groups

Patients will be randomly divided into two equal-sized groups. In one group, Dexamethasone will be prescribed at the dose of 8 mg after the spinal anesthesia, and the second group will receive 4 mg Ondansetron after the spinal anesthesia.

Main outcome variables

Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180210038681N1**
Registration date: **2018-05-01, 1397/02/11**
Registration timing: **registered_while_recruiting**

Last update: **2018-05-01, 1397/02/11**
Update count: **0**

Registration date

2018-05-01, 1397/02/11

Registrant information

Name

Jahanbahsh Rezanejadei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 3322 6226

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-29, 1396/11/09

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
A comparative study of the effects of Dexamethasone and Ondansetron on nausea and vomiting in cesarean section under spinal anesthesia by Bupivacaine (Marcaine)

Public title
The effect of dexamethasone and endonestrone premedication on the incidence of nausea and vomiting after cesarean section

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All patients who have attended for elective cesarean section In the ASA class one and two being in fertility age Patients with normal, mild or moderate stress, anxiety and depression level Patients who will undergo spinal anesthesia with bupivacaine 0.5%

Exclusion criteria:
Patients suffering from pregnancy toxicity (eclampsia-preclampsia) or history of motion sickness, history of meniere disease, and migraine BMI greater than 40 history of PONV(post opreative neusea and vomiting) severe or very severe level Stress , anxiety and depression Cigarette smoking and opoid drug consumption Patients that donot to cooperate Patients who undergo spinal anesthesia with lidocaine 5% Patients who receive atropine during opreation

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples were selected purposefully and were assigned to the study groups using the stratified randomized blocks. nullipara/multi para pregnancy is considered as strata in this study.

Blinding (investigator's opinion)
Double blinded

Blinding description
The Anesthesiologist was not aware of the type of drug used to prevent nausea and vomiting. The information was provided as a checklist and given to the inquirer who was not informed about the type of drugs for the patients. The incidence of nausea and vomiting in the patient was recorded 0 , 2 and 6 hours later in the PACU.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Lorestan University of Medical Sciences

Street address
Haj Karim Asali charity Hospital, at the begining of Felestin alley, Doctor Shariati Avenue

City
Khorramabad

Province
Lorestan

Postal code
6819789741

Approval date
2017-07-31, 1396/05/09

Ethics committee reference number
IR.LUMS.REC.1396.290

Health conditions studied

1

Description of health condition studied
nausea and vomiting

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Nausea

Timepoint
In PACU (at 0 oclock) and 2 oclock and after 6 oclock, the incidence of nausea and vomiting in the patient

Method of measurement
VAS (Visual analog scale)

2

Description
Vomiting

Timepoint
At PACU (at the begining) and 2 hours and 6 hours later

Method of measurement
Interview with patient

3

Description
Stress, depression and anxiety
Timepoint
In the recovery before surgery
Method of measurement
Depression, Anxiety, Stress Scale (DASS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group (1) used single bolus dose of Dexamethasone (8 mg) simultaneously with prep and drep, after spinal anesthesia with bupivacaine (0.5%) and spinal needle 25 gauge.
Category
Treatment - Drugs

2

Description
Intervention group (2) used single bolus dose of ondansetrone (4 mg) simultaneously with prep and drep, after spinal anesthesia with bupivacaine (0.5%) and spinal needle 25 gauge.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Haj Karim Asali charity Hospital
Full name of responsible person
Jahanbakhsh Razandehadi
Street address
Haj Karim Asali charity Hospital, at the begining of Felestin alley, Doctor Shariati Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
Jahanbashksh Rezanejadei
Street address
Paramedicine and Nutriton Campus , Next to the social security hospital , eastern Goldasht, Khorramabad , Lorestan
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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
Khoram-Abad 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
Khoram-Abad University of Medical Sciences
Full name of responsible person
Jahanbahsh rezanejadei
Position
eduactor
Latest degree
Master
Other areas of specialty/work
Anesthesiology
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Person responsible for scientific inquiries

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Latest degree

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Other areas of specialty/work

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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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The patients are divided into two groups A and B, and personal information of the patients remains confidential with the researcher.

When the data will become available and for how long

After completing the study, the information is presented in an article and immediately available to the public.

To whom data/document is available

The results are publicly available after printing and publication.

Under which criteria data/document could be used

An analysis of the data delivered is authorized by the written permission of the persons in the article.

From where data/document is obtainable

After publication of the article, people can submit articles by visiting Khorramabad University of Medical Sciences or through their respective websites.

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

Immediately after referring to the Khorramabad University of Medical Sciences or the relevant websites, the article is available to the referring.

Comments