

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

The effect of dexamethasone in control of postoperative nausea and vomiting in cesarean section surgery

Protocol summary

Study aim

Reduction of nausea and vomiting after surgery

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 2 on 60 patients. spss software was used for randomization.

Settings and conduct

This study will be a double-blind, randomized controlled clinical trial in which the patient and the anesthesiologist are unaware of the type of injected drug. The present study includes patients visiting the center. Razi medical training in Ahvaz province in the year 1402-1401, which has an indication for cesarean section and they are placed under spinal anesthesia under cesarean section. To carry out this plan, 60 patients will be considered for cesarean section with spinal anesthesia in the operating room. In this study, two groups, including group D, which receives 0.1 mg/kg of dexamethasone, and group p, which includes recipients of the same amount of normal saline, will be included as the placebo group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with cesarean indications; Consent to participate in the study; Age range from 18 to 40 years; Adequate level of anesthesia; ASA class 1 and ASA class 2; No history of HTN pregnancy. Exit criteria: Lack of patient consent to participate in the study; Reaching the level of anesthesia above T4; Patients with pre-pregnancy hypertension, pre-eclampsia and eclampsia; Presence of drug allergy.

Intervention groups

In this study, two groups, including group D, which receives 0.1 mg/kg of dexamethasone, and group p, which includes recipients of the same amount of normal saline, will be included as the placebo group. And the effect of the drug is measured in reducing nausea and vomiting

Main outcome variables

Nausea; vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191025045235N1**

Registration date: **2023-08-22, 1402/05/31**

Registration timing: **registered_while_recruiting**

Last update: **2023-08-22, 1402/05/31**

Update count: **0**

Registration date

2023-08-22, 1402/05/31

Registrant information

Name

Seyedeh fatemeh Hosseinejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3443 5099

Email address

drhosseinejad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-21, 1402/01/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dexamethasone in control of postoperative nausea and vomiting in cesarean section surgery

Public title

the effect of dexamethasone on nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

pregnant woman with cesarean section indication age between 18 and 40 consent to participate in the study ASA class 1, ASA class 2 no history of heart disease

Exclusion criteria:

patient dissatisfaction numbness above T4 HTN before pregnancy, preeclampsia, eclampsia drug allergy a bleeding process that leads to generalization of the patient

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

People were divided into two groups completely randomly based on the random block permutation method. For example, for blocks of four, we imagined 6 blocks ABBA, AABB, ABAB, BABA, BBAA, BAAB, which should be n/4 We sampled from these blocks in the form of placement. The random sequence was obtained from the website www.sealedenvelope.com. Patients are entered in the order of entry.

Blinding (investigator's opinion)

Double blinded

Blinding description

the patient and the anesthesia technician are unaware of the type of injected drug. the medicine is already prepared and given to the technician

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Jondishapoor Ahvaz University of Medical Sciences

Street address

EmamKhomeini Hospital, Azadegan Street, Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

6155883505

Approval date

2023-03-21, 1402/01/01

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.183

Health conditions studied

1

Description of health condition studied

vomiting

ICD-10 code

R11.1

ICD-10 code description

Vomiting

Primary outcomes

1

Description

Severe nausea and vomiting after surgery

Timepoint

1,2,4,6,12 hours after surgery

Method of measurement

V&N score table

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Dexamethasone group, including 30 people, will be injected before surgery for the purpose of PONV prophylaxis by a trained anesthesiologist who will be unaware of the type of drug injected, then the patients will be under spinal anesthesia with a 25-gauge spinal needle in the L4 space. L5 with 12.5 mg marcaine. During the surgery, the frequency of nausea, vomiting and shivering, blood pressure, and heart rate will be recorded by him, and after the operation, these parameters will be recorded in the ward at 1, 2, 4, 6, and 12 hours. and vomiting, through the V&N scoring table. The patient's shivering score is also recorded

Category

Treatment - Drugs

2

Description

Control group: before surgery, normal saline group including 30 people will be injected for prophylaxis of PONV by a trained anesthesiologist, who will be unaware of the type of drug injected, then the patients will be under spinal anesthesia with a 25 gage spinal needle in the L4 space. - L5 with 5.12 mg marcaine. During the surgery, the frequency of nausea, vomiting and shivering, blood pressure, and heart rate will be recorded by him, and after the operation, these parameters will be recorded in the ward at 1, 2, 4, 6, and 12 hours. and vomiting, through the V&N scoring table. The patient's shivering score is also recorded

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi hospital

Full name of responsible person

Seyedeh Fatemeh Hosseininejad

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Emam Khomeini ,Azadegan Street,Ahwaz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Jundishapur University of Ahvaz

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

Ahvaz University of Medical Sciences

Full name of responsible person

Seyedeh Fatemeh Hosseininejad

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Full name of responsible person

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Position

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Latest degree

Specialist

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

Ahvaz University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

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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

All data is potentially shareable after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

It will be available for researchers working in academic and scientific institutions

Under which criteria data/document could be used

Age, hemodynamics of the patient. The degree of response to the drug

From where data/document is obtainable

Through the published article

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

Email a request or receive information from a published article

Comments