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 Hosseininejad
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 61 3443 5099
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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 womanwith 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.sealedenevelope.com. Patients are entered in the order of entry.
Blinding (investigator's opinion)
Double blinded
Blinding description
the patient and the anesthesia technician are unware of the type of injected drug.the medicine is already prepare 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
Ahwaz
Province
Khouzestan
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
1,2,4,6,12hours 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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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