Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The adjuvant effect of dexamethasone to ondansetron or metoclopramide in prevention of nausea and vomiting after spinal anesthesia for elective caesarian section

Protocol summary

Study aim
The adjuvant effect of dexamethasone to ondansetron or metoclopramide in the prevention of nausea and vomiting after spinal anesthesia for elective cesarean section.

Design
This study will be done in the operating room. All of the drugs solution of this study will be prepared by only one person who is aware of the study's grouping, in 5 ml syringes in the same shape. Anesthesiologist, patients, and all medical staff that will collaborate in the study will not aware of the drug allocated to each patient.

Settings and conduct
In the present double-blind clinical trial, which will be carried out in a parallel way, a total of 150 patients who will be undergoing elective cesarean section under spinal anesthesia will be enrolled. Eligible patients will be randomly allocated into two equal A and B groups by block randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria: adult female with ASA class I or II, age between the 18 and 35, who are planned to undergo elective cesarean section under spinal anesthesia. Exclusion criteria: ASA class of III or IV, Allergies to local anesthetics and study medication, Hypertension caused by pregnancy, Patients whom emergency cesarean section is required.

Intervention groups
Intervention group 1 or DO group: dexamethasone 8 mg (manufactured by Tehran-Shimi Company) IV plus ondansetron 4 mg (manufactured by Caspin Company) is administered intravenously 10 minutes before anesthesia; Intervention group 2 or group DM: dexamethasone (manufactured by Tehran-Shimi Company) 8 mg IV, metoclopramide (manufactured by Caspin Company) 10 mg IV administered intravenously 10 minutes before anesthesia.

Main outcome variables
Nausea and Vomiting

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20221127056627N1**
Registration date: **2022-12-04, 1401/09/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-12-04, 1401/09/13**
Update count: **0**

Registration date
2022-12-04, 1401/09/13

Registrant information
Name
Zeinabsadat Fattahi Saravi
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3647 4270
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-11-21, 1401/08/30
Expected recruitment end date
2023-05-20, 1402/02/30
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The adjuvant effect of dexamethasone to ondansetron or metoclopramide in prevention of nausea and vomiting after spinal anesthesia for elective caesarian section

Public title

Survey the effect of adding dexamethasone to ondansetrone or metoclopramide to increase the effect of these drugs in prevention of nausea and vomiting after caesarian section under spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Adult women with ASA grade I or II (American Society of Anesthesiology classification) Women between 18 and 35 years old Women having elective caesarean section under spinal anesthesia

Exclusion criteria:

ASA class of III or IV pregnancy induced Hypertension Patients who have received steroid medication positive history of prolonged QT interval patients who refuced to do spinal anesthesia for her

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **150**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly allocated into two groups by block randomization. In this technique, a permutation block of size 6 will be made for patients of two groups A & B. In each block, equal numbers for two groups will be considered in alternative positions. Then 25 blocks of size 6 will be selected randomly and patients will be allocated randomly and equally into three groups according to these permutation block. block sequence will be prepare by www.sealedenvelope.com.

Blinding (investigator's opinion)

Double blinded

Blinding description

Antiemetic drugs are provided in the form of syringes containing 5 ml of normal saline solution by the first person, these drugs, which have the same color and size and in similar colors, are injected by the second person who is completely unaware of the contents of the syringes. The anesthesiologist, patients, and other personnel involved in the work are blinded to the drugs injected in this study. This study is double-blind

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz Medical School

Street address

3rd Floor, 3rd buiding of the Shiraz Medical School, Zand Blvd.

City

Shiraz

Province

Fars

Postal code

197871345

Approval date

2022-07-16, 1401/04/25

Ethics committee reference number

IR.SUMS.MED.REC.1401.216

Health conditions studied

1

Description of health condition studied

esarean section

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

Nausea

Timepoint

3 minutes and 15 minutes before the operation and 4 hours after the operation

Method of measurement

Score points based on Bellavia criteria

2

Description

Vomiting

Timepoint

3 minutes and 15 minutes before the operation and 4

hours after the operation.

Method of measurement

Score points based on Bellavia criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 or DO group: dexamethasone 8 mg (manufactured by Tehran-Shimi Company) IV plus ondansetron 4 mg (manufactured by Caspin Company) is administered intravenously ten minutes before anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group 2 or group DM: dexamethasone 8 mg((Manufactured by Tehran-Shimi Company) intravenously., and metoclopramide 10 mg (Made by Caspian Company) administered intravenously 10 minutes before anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghadir Mother and Child Hospital

Full name of responsible person

Mojtaba Soukhakian

Street address

Ghadir Mother and Child Hospital-the beginning of Golshan town -above the Quran gate -Shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Mahtab Memarpoor

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7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mojtaba Sookhakian

Position

Anesthesiology resident/physician

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person
Zeinabsadat Fattahi

Position
Pediatric Anesthesiology Fellowship

Latest degree
Subspecialist

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Anesthesiology

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Person responsible for updating data

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Research Assisstant

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Medical Informatics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It is against our policy

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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