Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparing the effect of Metoclopramide and ondansetron for preventing nausea and vomiting after cesarean section

Protocol summary

Study aim
Comparison of metoclopramide and ondansetron for preventing nausea and vomiting after cesarean section

Design
Phase-III double-blind, randomized placebo-controlled trial with 3 parallel groups on 150 patients; randomization will be done with sealed envelopes

Settings and conduct
This study will be performed on 150 candidates of elective cesarean referred to the obstetric and gynecology wards fo Khalij Fars and Shariati Hospitals, Bandar Abbas. Patients will be randomized into 3 groups. Patients in the first intervention group will receive metoclopramide, the second intervention group ondansetron, and the control (placebo) group normal saline intravenously. Given that the drugs will be prepared in similar vials by an individual uninvolved in the study, the patients, nurses, investigator, and outcome assessor will be blinded to patient groupings (double-blind).

Participants/Inclusion and exclusion criteria
Inclusion criteria: age of 18-40 years old, ASA class I and II, candidate for elective cesarean section, singleton and term pregnancy. Non-inclusion criteria: contraindications of spinal anesthesia, history of postoperative nausea and vomiting, history of severe motion sickness, history of opioid abuse, gestational hypertension, preeclampsia, history of taking antiemetics one week before surgery

Intervention groups
Intervention group 1: intravenous metoclopramide 10 mg/2 ml (DarouPakhsh Co., Iran) diluted with 8 ml normal saline Intervention group 2: intravenous ondansetron 4 mg/2 ml (Exir Co., Iran) diluted with 8 ml normal saline Control (placebo) group: 10 ml normal saline

Main outcome variables
Postoperative nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220502054722N1**
Registration date: **2022-11-26, 1401/09/05**
Registration timing: **retrospective**

Last update: **2022-11-26, 1401/09/05**
Update count: **0**

Registration date
2022-11-26, 1401/09/05

Registrant information

Name
Hasan Movahedi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3371 0370

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20goodlife2020@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-22, 1401/05/31

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effect of Metoclopramide and ondansetron for preventing nausea and vomiting after cesarean section

Public title
Metoclopramide versus ondansetron for preventing nausea and vomiting after cesarean section
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Age of 18-40 years old ASA class I and II Term and singleton pregnancy Candidacy for elective cesarean section
Exclusion criteria:
Contraindications of spinal anesthesia History of postoperative nausea and vomiting History of severe motion sickness Gestational hypertension History of opioid abuse Preeclampsia History of taking antiemetics one week before surgery Less than six hours fasting before surgery Emergency cesarean section
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization with individuals as units of randomization along with allocation concealment: 150 opaque envelopes and 150 cards with the names of the groups (A, B, C) will be prepared (50 cards for each group). The cards will be put into the envelopes, and the envelopes will be sealed and provided to the investigator. Upon entrance of each patient to the study, the envelopes will be shuffled, and one will randomly be selected. The patient will be allocated to groups A, B, or C based on the card inside the selected envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Metoclopramide, ondansetron, and normal saline have the same color, and an identical volume of these drugs (10 ml) will be administered. These drugs will be prepared in similar vials by an individual uninvolved in the study. Therefore, the patients, the caregivers, the investigator, and the outcome assessor will be unaware of the injected drug for each patient.
Placebo
Used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Hormozgan University of Medical Sciences
Street address
Faculty of Medicine, in front of Kargaran Sports Complex, Imam Hossein Blvd.
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2020-11-23, 1399/09/03
Ethics committee reference number
IR.HUMS.REC.1399.419

Health conditions studied

1

Description of health condition studied
Post-operative nausea and vomiting
ICD-10 code
R11.2
ICD-10 code description
Nausea with vomiting, unspecified

Primary outcomes

1

Description
Postoperative nausea and vomiting
Timepoint
At 1, 2, 4, and 6 hours after surgery
Method of measurement
Number of episodes and severity using a visual analog scale

Secondary outcomes

1

Description
Hypotension
Timepoint
Before surgery and at 1, 2, 4, and 6 hours after surgery
Method of measurement
Using a standard sphygmomanometer

2

Description
Diastolic blood pressure
Timepoint
Before surgery and at 1, 2, 4, and 6 hours after surgery
Method of measurement
Using a standard sphygmomanometer

3

Description
Heart rate
Timepoint
Before surgery and at 1, 2, 4, and 6 hours after surgery
Method of measurement
Counting the heart beat per minute

Intervention groups

1

Description
Intervention group 1: 5 minutes before spinal anesthesia, intravenous metoclopramide 10 mg/2 ml (DarouPakhsh Co., Iran) diluted with 8 ml normal saline will be injected within 2 minutes
Category
Prevention

2

Description
Intervention group 2: 5 minutes before spinal anesthesia, intravenous ondansetron 4 mg/2 ml (Exir Co., Iran) diluted with 8 ml normal saline will be injected within 2 minutes
Category
Prevention

3

Description
Control group: 5 min before spinal anesthesia, 10 ml normal saline (placebo) will be injected within 2 minutes
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital, Bandar Abbas
Full name of responsible person
Hasan Movahedi
Street address
Dr. Ali Shariati Hospital, Next to the Revolutionary Court, Shahid Naser Blvd., Bandar Abbas, Hormozgan
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2

Recruitment center
Name of recruitment center
Khalij Fars Hospital, Bandar Abbas
Full name of responsible person
Hasan Movahedi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellery for Research, Hormozgan University of Medical Sciences
Full name of responsible person
Teamur Aghamolaei
Street address
Faculty of Medicine, Across from Kargaran Sports Complex, Imam Hossein Blvd.
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Email
teaghamolaei@gmail.com
Web page address
https://resv.hums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Vice-Chancellery for Research, Hormozgan 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
Bandare-abbas University of Medical Sciences

Full name of responsible person
Hasan Movahedi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Shahid Mohammadi Hospital, Jomhouri Eslami Blvd., Hormozgan, Iran

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available