

# 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 of 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)

##### Phone

+98 76 3371 0370

##### Email address

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

##### **City**

Bandar Abbas

##### **Province**

Hormozgan

##### **Postal code**

7916613885

##### **Phone**

+98 76 3333 5934

##### **Email**

20goodlife2020@gmail.com

##### **Web page address**

<https://dshh.hums.ac.ir/>

## 2

#### **Recruitment center**

##### **Name of recruitment center**

Khalij Fars Hospital, Bandar Abbas

##### **Full name of responsible person**

Hasan Movahedi

##### **Street address**

Khalij Fars Hospital, Azad University Blvd., Bandar Abbas, Hormozgan

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##### **Postal code**

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##### **Phone**

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##### **Email**

20goodlife2020@gmail.com

## **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.

##### **City**

Bandar Abbas

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##### **Postal code**

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##### **Phone**

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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

**Street address**

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

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**Phone**

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## Person responsible for scientific 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

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## Person responsible for updating data

**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**

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**Phone**

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**Email**

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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