

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of effect of ondansetron plus dexamethasone and metoclopramide plus dexamethasone on postoperative nausea and vomiting in Gynecological Laparoscopic Surgery

#### Protocol summary

##### Study aim

1. Determination of nausea and vomiting after laparoscopic surgery in women in ondansetron-dexamethasone group 2. Determination of nausea and vomiting after laparoscopic gynecologic surgery in metoxlopramide-dexamethasone group

##### Design

Randomised, superiority, parallel group trial with blinded outcome assessment. Balanced block randomization(random blocks). In each block, 2 patients are randomly assigned random codes A and B.

##### Settings and conduct

The study was performed at the Women's Surgery Center at Besat Hospital in Sanandaj. In this study, to compare the effects of postoperative nausea and vomiting 15 minutes before surgery, the first group received ondansetron 4mg plus dexamethasone 8mg and the second group received 10mg metoclopramide plus dexamethasone 8mg intravenously to patients undergoing laparoscopic surgery under General anesthesia will be prescribed.

##### Participants/Inclusion and exclusion criteria

Fasting for 8 hours before surgery, ASA 1&2 classification, Not having a history of co-existing diseases such as: cardiovascular, respiratory, neurological, diabetes, gastrointestinal diseases and motion sickness

##### Intervention groups

The first group will receive 4mg ondansetron plus 8mg dexamethasone intravenously. The second group will receive 10 mg of metoclopramide plus 8 mg of dexamethasone intravenously.

##### Main outcome variables

1. The rate of nausea and vomiting after laparoscopic surgery

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171216037910N2**

Registration date: **2019-08-31, 1398/06/09**

Registration timing: **retrospective**

Last update: **2019-08-31, 1398/06/09**

Update count: **0**

##### Registration date

2019-08-31, 1398/06/09

##### Registrant information

##### Name

Arvin Barzanji

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 87 3334 2561

##### Email address

arvin.barzanji1988@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-06-10, 1396/03/20

##### Expected recruitment end date

2017-09-21, 1396/06/30

##### Actual recruitment start date

2017-06-22, 1396/04/01

##### Actual recruitment end date

2018-05-02, 1397/02/12

##### Trial completion date

2018-05-04, 1397/02/14

## Scientific title

Comparison of effect of ondansetron plus dexamethasone and metoclopramide plus dexamethasone on postoperative nausea and vomiting in Gynecological Laparoscopic Surgery

## Public title

The effect of ondansetron and metoclopramide on postoperative nausea and vomiting in Gynecological Laparoscopic Surgery

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Fasting for 8 hours before surgery ASA classification 1& 2  
No history of co-existing disease: cardiovascular, respiratory, diabetes, gastrointestinal and motion sickness.

### Exclusion criteria:

History of post operative nausea and vomiting  
emergency surgery Become an open surgical procedure

## Age

From **18 years** old

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

Actual sample size reached: **61**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Balanced (permuted) block randomization(random blocks). In each block, 2 patients are randomly assigned random codes A and B, and according to the corresponding code, they receive the dose and the desired drug or placebo.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study (metoclopramide and ondansetron) were prepared and coded by an anesthetist who was not involved in the study. At the specified time, the coded drugs plus dexamethasone were administered by an anesthesiologist who was not involved in the study. Patients were evaluated by trained nurses who were not aware of the grouping of patients.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

##### Street address

Faculty of Medicine, Kurdistan University of Medical Sciences, Pasdaran Blvd.

##### City

Sanandaj

##### Province

Kurdistan

##### Postal code

6617713446

#### Approval date

2017-05-14, 1396/02/24

#### Ethics committee reference number

IR.MUK.REC.1396/29

## Health conditions studied

### 1

#### Description of health condition studied

Post operative nausea and vomiting

#### ICD-10 code

R11

#### ICD-10 code description

Nausea and vomiting

## Primary outcomes

### 1

#### Description

Post operative nausea and vomiting

#### Timepoint

Emergence of anesthesia (time zero), on arrival to recovery, and at 2, 4, 6, 12 and 24 hours after surgery

#### Method of measurement

Visual Analogue Scale

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Intravenous administration of 4mg ondansetron plus 8mg dexamethasone.

#### Category

Prevention

**2**

**Description**

Intervention group: Intravenous administration of 10mg metoclopramide with 8mg dexamethasone.

**Category**

Prevention

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Besat hospital

**Full name of responsible person**

Khadijeh Daseh

**Street address**

Merdoux Crossroads- Keshavarz Street

**City**

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besathospital@muk.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Ebrahim Ghaderi

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Faculty of Medicine, Kurdistan University of Medical Sciences, Pasdaran Blvd.

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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**

Sanandaj 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**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Khadijeh Daseh

**Position**

Anesthesit

**Latest degree**

Bachelor

**Other areas of specialty/work**

Anesthesiology

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Paramedical faculty, Medical University of Kurdistan, Pasdaran Blvd

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**Latest degree**

Bachelor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Sanandaj University of Medical Sciences

**Full name of responsible person**

Arvin Barzanji

**Position**

Lecturer

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

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**Fax****Email**

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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**

No more information.

**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**

Not applicable