

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

Sanandaj

Province

Kurdistan

Postal code

6618634683

Phone

+98 87 3328 5910

Email

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

Street address

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

City

Sanandaj

Province

Kurdistan

Postal code

6614713446

Phone

+98 87 3366 4351

Email

f.rezaee@muk.ac.ir

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

Street address

Paramedical faculty, Medical University of Kurdistan, Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6614713446

Phone

+98 87 3334 2561

Email

fereshtehdaseh@yahoo.com

Person responsible for scientific 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

Street address

Paramedical faculty, Medical University of Kurdistan, Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6614713446

Phone

+98 87 3334 2561

Email

fereshtehdaseh@yahoo.com

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

Street address

Faculty of Paramedicine, Medical University of
Kurdistan, Pasdaran Blvd

City

Sanandaj

Province

Kurdistan

Postal code

6616994745

Phone

+98 87 3334 2561

Fax**Email**

arvin.barzanji1988@gmail.com

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