Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of effect of ondansetrone 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

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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 ondansetrone plus dexamethasone and metoclopramide plus dexamethasone on postoperative nausea and vomiting in Gynecological Laparoscopic Surgery

Public title
The effect of ondansetrone 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
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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
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Person responsible for updating data

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Lecturer

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Master

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Nursery

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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