Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of dexmedetomidine and dexamethasone efficacy in preventing postoperative nausea and vomiting after laparotomic hysterectomy

Protocol summary

Study aim
Comparison of dexmedetomidine and dexamethasone efficacy in preventing postoperative nausea and vomiting after laparotomic hysterectomy

Design
A single-blind, randomized clinical trial study with parallel groups and phases 3 on 165 patients. Randomization will be done with the block randomization method using Random allocation software.

Settings and conduct
This study will be conducted on patients candidates for laparotomic hysterectomy in Urmia Kowsar Hospital. Patients will be divided into three groups of dexamethasone, dexmedetomidine and ondansetron. This study will be a single-blind study and the patient will be blinded to her allocation into one of groups.

Participants/Inclusion and exclusion criteria
In this study, 165 patients candidates for laparotomic hysterectomy in the age range of 18-65 years will be included. The main exclusion criteria will be receiving any anti-nausea and vomiting medication within 24 hours before surgery, BMI above 35 kg/m2, and being allergic to any of the drugs used in this study.

Intervention groups
Patients in the first group will receive 8 mg of dexamethasone , in the second group 1 microg/kg dexmedetomidine and in the third group (control group) 0.15 ml/kg intravenously and in a single dose after induction of anesthesia and before skin incision.

Main outcome variables
Frequency of nausea and vomiting; severity of nausea and vomiting.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170516033992N15**
Registration date: **2024-10-10, 1403/07/19**
Registration timing: **prospective**

Last update: **2024-10-10, 1403/07/19**
Update count: **0**

Registration date
2024-10-10, 1403/07/19

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 44 3222 2010
Email address
karami.t@umsu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-21, 1403/09/01

Expected recruitment end date
2025-07-22, 1404/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of dexmedetomidine and dexamethasone efficacy in preventing postoperative nausea and vomiting after laparotomic hysterectomy

Public title
Investigating the effect of dexamethasone and Dexmedetomidine in preventing nausea and vomiting after hysterectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Elective laparotomic hysterectomy Age between 18 and 65 years
Exclusion criteria:
Receiving any anti-nausea and vomiting medication in 24 hours before surgery BMI (Body mass index) above 35 kg/m2 Having allergy to any of the drugs used in this study
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **165**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into interventions and control groups using block randomization based on generated numbers by Random allocation software. Thus, in this software, first the number of groups (3 groups) and the total number of the sample size will be entered, and then in the block section, the Block randomization method will be selected. Patients will be allocated in intervention or control groups based on generated numbers. According to the total sample size (65 patients in each group), 28 blocks of 6 will be used.
Blinding (investigator's opinion)
Single blinded
Blinding description
The study will be conducted as a single-blind clinical trial. The patient the will be blind to the her allocation into interventions or control groups. Syringes containing drugs will be similar in shape and size.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Urmia University of Medical Sciences
Street address
Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Approval date
2024-03-13, 1402/12/23
Ethics committee reference number
IR.UMSU.REC.1403.006

Health conditions studied

1

Description of health condition studied
Post-operative nausea and vomiting
ICD-10 code
F50.5
ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Having nausea and vomiting
Timepoint
Within 24 hours after the surgery
Method of measurement
Feeling the need to empty the contents of the stomach

2

Description
Severity of nausea and vomiting
Timepoint
Within 24 hours after the surgery
Method of measurement
Visual analogue scale (VAS)

Secondary outcomes

1

Description
Fentanyl dosage
Timepoint
Based on the dose of fentanyl received during anesthesia
Method of measurement
Milligrams

Intervention groups

1

Description
Intervention group: Patients in the first group will receive 8 mg of dexamethasone intravenously in a single dose after induction of anesthesia and before skin incision.
Category
Treatment - Drugs

2

Description
Intervention group: Patients in the second group will receive 1 µg/kg dexmedetomidine intravenously in a single dose after induction of anesthesia and before skin incision.
Category
Treatment - Drugs

3

Description
Control group: Patients in the third group will receive 0.15 ml/kg of ondansetron intravenously in a single dose after induction of anesthesia and before skin incision.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Urmia Kowsar Hospital
Full name of responsible person
Dr.Tohid Karami
Street address
Hassani Ave, Kowsar hospital, Urmia,Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Saber Gholizadeh
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Urmia University of Medical Sciences, Resalat street, Jahad Blvd., Urmia, Iran.
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr.Tohid Karami
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
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Kowsar hospital, Hassani Ave, Urmia, Iran.
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Person responsible for updating data

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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
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable