Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jul 2026

Preventive effect of intravenous dexamethasone on nausea, vomiting and pain after laparoscopic ovarian cystectomy

Protocol summary

Study aim
Preventive effect of intravenous dexamethasone on nausea and vomiting after laparoscopic ovarian cystectomy

Design
A randomized double-blinding clinical trial, with the parallel groups

Settings and conduct
In this study, 88 patients who are candidates for laparoscopic cystectomy will be included in the study and will be randomly divided into two groups. Dexamethasone will be given intravenously in one group and normal saline in the other. Patients' nausea and vomiting are then assessed.

Participants/Inclusion and exclusion criteria
Inclusion criteria are women candidates for laparoscopic cystectomy, with ASA 2 and obtaining informed consent to participate in the study. Exclusion criteria included contraindications to use of dexmetazone, severe and uncontrolled cardiovascular, renal, hepatic, chronic respiratory disease, use of antiemetic and analgesic drugs in the 24 hours before surgery, pregnant or elderly women, people who describe the experience of gastrointestinal problems and postoperative nausea, or a history of corticosteroids, or a body mass index (BMI) of more than 30 kg / m2.

Intervention groups
Two minutes before the induction of anesthesia, the first group received 8 mg of dexamethasone (2 cc) and the second group received normal saline with the same volume (2 cc) intravenously. Then induction of anesthesia is performed with fentanyl 2 µg / kg, propofol 2 mg/kg, atracurium 0.5 mg/kg and ventilation is performed with a mask. Three minutes later, the patient is intubated with a 7.5 intubation tube. Continued anesthesia of the patient during surgery is provided with 0.8% isoflurane and 0.1 mg/kg morphine.

Main outcome variables
Severity of nausea; Severity of vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N7**
Registration date: **2020-10-08, 1399/07/17**
Registration timing: **prospective**

Last update: **2020-10-08, 1399/07/17**
Update count: **0**

Registration date
2020-10-08, 1399/07/17

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2021-04-19, 1400/01/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Preventive effect of intravenous dexamethasone on nausea, vomiting and pain after laparoscopic ovarian cystectomy

Public title
The effect of intravenous dexamethasone on nausea, vomiting and pain after laparoscopic ovarian cystectomy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being candidate for laparoscopic cystectomy ASA score of 2 according to American Society of Anesthesiologists Classification (ASA class) Informed consent to participate in the study
Exclusion criteria:
Contraindications to use of dexamethasone Having severe and uncontrolled diseases of cardiovascular, renal, hepatic, chronic respiratory Taking anti-nausea drugs and painkillers 24 hours before surgery People with a history of gastrointestinal problems and postoperative nausea Having a history of corticosteroids BMI>30 kg/m2 Pregnant and elderly women
Age
From **18 years** old to **65 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **88**
Randomization (investigator's opinion)
Randomized
Randomization description
88 eligible patients will be randomly selected. Then, these patients will be randomly encoded using computer software called "Random Allocation" and automatically divided into two groups. The relevant codes will be entered in the raw checklists and each of these checklists will be randomly assigned to one patient and that patient will be randomly assigned to one of the two study groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, dexamethasone and normal saline were pre-prepared by the operating room nurse in one volume and labeled A and B. It is then given daily to the researcher and will be used randomly for patients.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib Ave, Azadi Square.
City
Isfaha
Province
Isfehan
Postal code
8174673461
Approval date
2020-09-26, 1399/07/05
Ethics committee reference number
IR.MUI.MED.REC.1399.528

Health conditions studied

1

Description of health condition studied
Laparoscopic cystectomy
ICD-10 code
N83.2
ICD-10 code description
Other and unspecified ovarian cysts

Primary outcomes

1

Description
Severity of nausea
Timepoint
Zero, 2, 12 and 24 hours after surgery
Method of measurement
Visual Analogue Scale (VAS)

2

Description
Severity of vomiting
Timepoint
Zero, 2, 12 and 24 hours after surgery
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
Patient satisfaction
Timepoint
24 hours after surgery
Method of measurement

Score 0 as dissatisfied to score 5 as complete satisfaction

Intervention groups

1

Description

Control group: Patients in this group are given intravenous normal saline with the same volume (two cc) two minutes before induction of anesthesia. Then induction of anesthesia is performed with fentanyl 2 µg / kg, propofol 2 mg / kg and atracurium 0.5 mg / kg and ventilation is performed with a mask. Three minutes later, the patient is intubated with a 7.5 intubation tube. Continued anesthesia of the patient during surgery is provided with 0.8% isoflurane and 0.1 mg / kg morphine.

Category

Placebo

2

Description

Intervention group: Patients in this group are given 8 mg of dexamethasone (2 cc) intravenously two minutes before induction of anesthesia. Then induction of anesthesia is performed with fentanyl 2 µg / kg, propofol 2 mg / kg and atracurium 0.5 mg / kg and ventilation is performed with a mask. Three minutes later, the patient is intubated with a 7.5 intubation tube. Continued anesthesia of the patient during surgery is provided with 0.8% isoflurane and 0.1 mg / kg morphine.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Beheshti Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Lili Adineh Mehr
Position
Professor
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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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available