

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 dexamethasone, 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)

Phone

+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

Isfahan

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

Lili Adineh Mehr

Street address

Anesthesiology Department, Shahid Beheshti Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Vice Chancellor for Research, School of Medicine,
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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

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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