Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Intraperitoneal dexamethasone: a new method for preventing nausea and vomiting after gynecological laparoscopic surgery

Protocol summary

Study aim
effects of Intra-peritoneal Dexamethasone on preventing nausea/vomiting after laparoscopic gynecologic surgeries.

Design
double-blind randomised control trial with parallel groups,80 people will be assigned to two equal groups with block design randomisation

Settings and conduct
This study will be performed on 80 ASA-grade female patients in grades 1 and 2 who are candidates for elective gynecologic laparoscopic surgery in Shahid Sadoughi Hospital (in Yazd, Iran) between the ages of 18 and 70 years. In the first group, 20 cc normal saline is sprayed in the diaphragm and peritoneal cavity after surgery and before the removal of trocar. In the second group, 20 cc normal saline containing 16 mg dexamethasone will be sprayed in the diaphragm and peritoneal cavity after surgery and before removal of trocar. The patient will be ex-tubated and transported to recovery after appropriate alertness and breathing. The patient and the person follow the patient and filling out the questionnaire will not be informed of any of the medications used (dexamethasone or placebo).After surgery, the frequency of nausea and vomiting is measured at 1, 2, 4, 12, 18, 24 hours.

Participants/Inclusion and exclusion criteria
Inclusion criteria: women aged 18 to 70 years old with ASA class 1 or 2 who are candidates for elective gynecologic laparoscopic surgery. Exclusion criteria: body mass index >30, diabetes or other underlying diseases, histories of abdominal surgery or chronic pain, consuming anti-emetic drugs within 48 hours before surgery, history of long-term analgesics therapy, addiction, as well as allergy to anesthetic drugs and dexamethasone were considered as exclusion criteria.

Intervention groups
Intervention group receives 16 mg intra-peritoneal dexamethasone in 20 ml normal saline and placebo group receives 20 cc normal saline intra-peritoneally

Main outcome variables
Nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180702040309N1**
Registration date: **2020-05-14, 1399/02/25**
Registration timing: **prospective**

Last update: **2020-05-14, 1399/02/25**
Update count: **0**

Registration date
2020-05-14, 1399/02/25

Registrant information

Name
Zahra Ghodratipour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3823 6326

Email address
zahra.ghodratipour@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-21, 1399/03/01

Expected recruitment end date
2020-07-10, 1399/04/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intraperitoneal dexamethasone: a new method for preventing nausea and vomiting after gynecological laparoscopic surgery

Public title

Effect of intra-peritoneal Dexamethasone on Nausea and Vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Aged 18 to 70 years old Female gender Class 1 or 2 of American Society of Anesthesiologists Classification Candidates for elective gynecologic laparoscopic surgery

Exclusion criteria:

Body mass index (BMI) >30, diabetes or other underlying diseases histories of abdominal surgery or chronic pain consuming antiemetic drugs within 48 hours before surgery history of long-term analgesics therapy Addiction to any kinds of substances allergy to anesthetic drugs and dexamethasone

Age

From **18 years** old to **70 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Given the sample size of 80 people, Sampling will be done in 20 blocks of four. In each block, two individuals will be randomly assigned to the intervention group and two others to the control group, so that all six states of a four-block may be selected ten times randomly from the blocks. By the end, forty people in each group will be randomly assigned.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drug and placebo will be prepare and coded in uniform syringes. A person who is not informed about the contain of each syringe administer the drugs.Researchers who are unaware about the drugs and patients of each group will record the data.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Yazd University of Medical Sciences

Street address

Vice Chancellor for Research, Central Administration, Bahonar Sq., Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2017-03-04, 1395/12/14

Ethics committee reference number

5301

Health conditions studied

1

Description of health condition studied

gynecological laparoscopy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

nausea score

Timepoint

1, 2, 4, 12, 18, 24 hours after surgery

Method of measurement

No - mild - moderate - severe

2

Description

vomiting score

Timepoint

1, 2, 4, 12, 18, 24 hours after surgery

Method of measurement

None - 1 time - 2 or 3 times - more than 3 times

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 20 ml normal salin containing dexamethasone (16 mg) were injected into diaphragm and peritoneal cavity after the surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi hospital
Full name of responsible person
Zahra Ghodratipour
Street address
Shahid Ghandi Blvd, Safaieh, Yazd, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
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dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
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medical doctor
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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 necessity for publishing the raw data.

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