

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 Ghodrati-pour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3823 6326

Email address

zahra.ghodrati-pour@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 prepared and coded in uniform syringes. A person who is not informed about the content of each syringe administers 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

Ethics 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 saline 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

masoud mirzaei

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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

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

Full name of responsible person

Zahra Ghodratipour

Position

medical doctor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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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 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