Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

The effect of intra peritoneal and intravenous dexamethasone in reduce pain and nausea and vomiting after gynecology laparoscopic surgery.

Protocol summary

Study aim
The effect of intraperitoneal and intravenous dexamethasone in reduce pain and nausea and vomiting after gynecology laparoscopic surgery

Design
A randomized clinical trial with the parallel group. Phase 2-3 was performed on 60 patients with laparoscopic gynecological surgery, two-way, blind, randomized groups, and for randomization by the randomized block method.

Settings and conduct
This clinical trial study is performed in Shahid Akbarabadi Hospital in Tehran. Patients who need laparoscopic surgery due to a gynecological indication are included in the study. In the first intervention, group8 mg dexamethasone (2 CC) was intravenously injected. and 2 CC normal saline peritoneal cavity after surgery and before leaving the trocar was sprayed. In the second group 8 mg dexamethasone (2 CC) peritoneal cavity was sprayed, and 2 CC normal saline intravenously injected after surgery and before leaving the trocar was.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Ages between 18 and 60 years, Patients who need laparoscopic surgery due to a gynecological indication exclusion criteria: History of abdominal surgery, Extensive pelvic surgeries Body mass index(BMI) of more than 40(kg/m^2), Existence of diseases of the stomach and intestines, allergy to dexamethasone.

Intervention groups
8 mg dexamethasone (2 CC) intravenously injected. and 2 CC normal saline peritoneal cavity after surgery and before leaving the trocar was sprayed. 8 mg dexamethasone (2 CC) peritoneal cavity sprayed, and 2 CC normal saline intravenously injected after surgery and before leaving the trocar was

Main outcome variables
The severity of nausea, vomiting, and postoperative pain by Visual Analogue Scale (VAS)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160523028008N18**
Registration date: **2021-09-30, 1400/07/08**
Registration timing: **prospective**

Last update: **2021-09-30, 1400/07/08**
Update count: **0**

Registration date
2021-09-30, 1400/07/08

Registrant information

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-01, 1400/08/10

Expected recruitment end date
2022-02-20, 1400/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of intra peritoneal and intravenous dexamethasone in reduce pain and nausea and vomiting after gynecology laparoscopic surgery.

Public title
Effect of intraperitoneal and intravenous dexamethasone in reduce pain and nausea and vomiting after laparoscopic surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Ages between 18 and 60 years Patients who need laparoscopic surgery due to a gynecological indication

Exclusion criteria:
History of abdominal surgery Extensive pelvic surgeries Body mass index(BMI) of more than 40 Existence of diseases of the stomach and intestines Drug allergy to dexamethasone

Age
From **18 years** old to **60 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

Blinding (investigator's opinion)
Triple 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
Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat High Way

City
Tehran

Province
Tehran

Postal code
1168743514

Approval date
2020-11-14, 1399/08/24

Ethics committee reference number
IR.IUMS.FMD.REC.1399.575

Health conditions studied

1

Description of health condition studied
Laparoscopic surgical

ICD-10 code
Z53.31

ICD-10 code description
Laparoscopic surgical procedure converted to open procedure

Primary outcomes

1

Description
Severity of nausea

Timepoint
6, 12, 18 and 24 hours after surgery

Method of measurement
Visual Analogue Scale (VAS)

2

Description
Severity of vomiting

Timepoint
6, 12, 18 and 24 hours after surgery

Method of measurement
Visual Analogue Scale (VAS)

3

Description
Severity of pain

Timepoint
6, 12, 18 and 24 hours after surgery

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 8 mg dexamethasone (2 CC) intravenously injected. and 2 CC normal saline peritoneal cavity after surgery and before leaving the trocar was sprayed.
Category
Treatment - Drugs

2

Description
Intervention group: 8 mg dexamethasone (2 CC) peritoneal cavity sprayed, and 2 CC normal saline intravenously injected after surgery and before leaving the trocar was.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar Abadi Hospital
Full name of responsible person
Azadeh Akbari sene
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shahid Akbar Abadi Hospital, Ferdowsi Station, Molavi st, Tehran
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Sponsors / Funding sources

1

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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
Iran 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
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Azadeh Akbari sene
Position
Associate Professor
Latest degree
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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 plan to make this available

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