Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of dexamethasone versus placebo in the prevention of nausea and vomiting and postoperative pain in patients undergoing abdominal hysterectomy

Protocol summary

Study aim

Studying the effects of dexamethasone versus placebo in the prevention of nausea and vomiting and postoperative pain in patients undergoing abdominal hysterectomy.

Design

Clinical trial, placebo-controlled, with parallel groups, double-blinded, randomized with simple randomization

Settings and conduct

Patients are randomly assigned into two groups of 51 (single dose) dexamethasone 8 mg intravenous or normal saline (2 ml) as a placebo before surgery. In order to blindness dexamethasone (Tehran Chemistry Company) and saline were placed in a similar 2 ml syringe and placed at the disposal of the nurse for injection. After surgery, patients are transferred to recovery and are monitored for about 30 minutes. Pethidine is used to relieve pain in recovery patients.

Participants/Inclusion and exclusion criteria

This study is a double blind clinical trial. 102 patients over 30 years old with a BMI of 20-35 who are undergoing abdominal hysterectomy are included in the study. Exit criteria include patients with systemic diseases including diabetes, asthma, cancer, patients with a history of allergy or dexamethasone susceptibility, patients who had nausea and vomiting within 24 hours before surgery, patients who have gastrointestinal disturbances such as gastritis and esophagitis within 48 hours prior to anesthetic surgery.

Intervention groups

- Single dose of 8 mg intravenous dexamethasone infusion - Normal saline (2 ml)

Main outcome variables

- Prevalence of nausea and vomiting - Severity of nausea - Need for anti-nausea drugs in postoperative times - Severity of the pain felt by the patients is scored from 0 to 10. - Duration of the surgery - Duration of the hospital stay

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161220031487N8**
Registration date: **2018-04-08, 1397/01/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-04-08, 1397/01/19**
Update count: **0**

Registration date

2018-04-08, 1397/01/19

Registrant information

Name

مهرداد Mesbah kiaei

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 346 5866

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative study of dexamethasone versus placebo in the prevention of nausea and vomiting and postoperative pain in patients undergoing abdominal hysterectomy

Public title
Studying the effects of dexamethasone in the prevention of nausea and vomiting and postoperative pain in patients undergoing abdominal hysterectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age over 30 years Candidate for abdominal hysterectomy Body mass index (BMI) from 20-35
Exclusion criteria:
Systemic disease such as diabetes, asthma or cancer History of allergy to dexamethasone Nausea and vomiting in 24 hours prior to operation Receiving anti-emetics 48 hours before operation Digestive system anomalies such as gastritis and esophagitis

Age
From **30 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization using the Excel software random numbers function.

Blinding (investigator's opinion)
Double blinded

Blinding description
For blinding, Dexamethasone (Tehran Chemistry Company) and saline were placed in a similar 2 ml syringe before operation and provided to the nurse for injection.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of the Iran University of Medical Sciences

Street address
Next to Milad Tower, Iran University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
1416771818

Approval date
2017-03-17, 1395/12/27

Ethics committee reference number
IR.IUMS.REC1395.9311290003

Health conditions studied

1

Description of health condition studied
Hysterectomy

ICD-10 code
Z90.7

ICD-10 code description
Acquired absence of genital organ(s)

Primary outcomes

1

Description
Prevalence of nausea and vomiting

Timepoint
Measurement at 0، 2، 4، 6، 12 and 24 hours after operation

Method of measurement
The severity of nausea is from 0 to 10, a score of 0 indicates a lack of nausea, and 10 means a very severe nausea.

2

Description
Severity of pain felt by patients

Timepoint
Measured at 0, 2, 4, 6, 12 and 24 hours after operation

Method of measurement
The severity of the pain felt by the patients is scored from 0 to 10, with zero indicating the absence of pain and 10 means a very severe pain.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Single dose of 8 mg intravenous dexamethasone infusion

Category

Treatment - Drugs

2

Description

Control group: normal saline (2 ml)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar Hospital

Full name of responsible person

Shahla Amirzargar

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Behafarin st., Karimkhan st

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2

Recruitment center

Name of recruitment center

Shahid Akbar-Abadi Obstetrics and Gynecology Hospital

Full name of responsible person

Shahla Amirzargar

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr Seyed Kazem Malakouti

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Web page address

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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

Iran University of Medical Sciences

Full name of responsible person

Shahla Amirzargar

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available