

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

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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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2**Recruitment center****Name of recruitment center**

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Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

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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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Person responsible for updating data

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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