Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of the effect of intranasal dexamethasone on prevention of postoperative nausea and vomiting in hysterectomy

Protocol summary

Study aim
Comparison of the effect of nasal dexamethasone on post hysterectomy surgery nausea and vomiting prevention in adults

Design
Clinical trials in two community-based and pragmatic groups with parallel blinded, randomized, 35-person groups

Settings and conduct
Using intranasal dexamethasone and saline with a specific dose in two groups and comparing its effect on reducing nausea and vomiting after hysterectomy surgery in Shahid Beheshti Hospital and Alzahra Hospital, the patient and researcher are unaware of which drug is used for each patient

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women older than 18 years; American society of anesthesiologists(ASA) physical status classification 1 or 2 ; Filled informed consent form ; Hysterectomy under general anesthesia ; Exclusion criteria: Patient with sever and uncontroled cardiovascular , renal , liver and chronic lung diseases ; Systemic fungal infection ; Contraindication for dexamethasone ; Taking antiemetic and analgesics drugs during last 24 hours before surgery ; Pregnant women ; Menstural period ; Patients with motion sickness and GI problems and history of postoperative nausea and vomiting ; Patients with History of Psycologic Problem and Parkinson Disease ; History of Chemotherapy .

Intervention groups
Recipient of Dexamethasone (A) and Saline (B)

Main outcome variables
Incidence of nausea ; Score of nausea ; Incidence of vomiting ; Score of vomiting ; Score of pain ; First time using anti emetic drug ; Total dose of anti emetic ; Frequency of using anti emetic drug ; Extubation time ; Length of stay in recovery ; Patient satisfaction score ; Beginning time of using liquid foods ; Beginning time of using solid foods ; age ; Under treatment group ; Length of stay in hospital

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180416039326N13**
Registration date: **2020-06-15, 1399/03/26**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-15, 1399/03/26**
Update count: **0**

Registration date
2020-06-15, 1399/03/26

Registrant information

Name
Hamidreza Shetabi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3620 2020

Email address
hamidshetabi@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-14, 1399/03/25

Expected recruitment end date
2021-06-15, 1400/03/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparative study of the effect of intranasal dexamethasone on prevention of postoperative nausea and vomiting in hysterectomy

Public title
Effect of intranasal dexamethasone on prevention of postoperative nausea and vomiting in hysterectomy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Women older than 18 years American society of anesthesiologists(ASA) physical status classification 1 or 2 Filled informed consent form Hysterectomy under general anesthesia

Exclusion criteria:
Patient with sever and uncontroled cardiovascular ، renal ، liver and chronic lung diseases Systemic fungal infection Contraindication for dexamethasone Taking antiemetic and analgesics drugs during last 24 hours before surgery Pregnant women Menstural period Patients with motion sickness and GI problems and history of postoperative nausea and vomiting Patients with History of psycologic problem and Parkinson disease History of chemotherapy

Age
From **18 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Random allocation to intervention and control groups using Random allocation software.70 patients who have candidated for elective hysterectomy will divided randomly to intervention group who will recieve nasal dexamethasone (group A) and control group who will recieve nasal normal saline.

Blinding (investigator's opinion)
Double blinded

Blinding description
Anesthesiologist who has no function in collection of dates devides drugs in two groups A and B with same volume and then describes them . In this double-blind clinical trial the patient and the observer who records dates are unware of patients groups and drugs which are being studied but the analyzer is aware.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences

Street address
Hezar Jerib St

City
Esfahan

Province
Isfehan

Postal code
۷۳۴۶۱-۸۱۷۴۶

Approval date
2020-03-16, 1398/12/26

Ethics committee reference number
IR.MUI.MED.REC.1398.731

Health conditions studied

1

Description of health condition studied
Postoperative Nausea and Vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and Vomiting

Primary outcomes

1

Description
Incidence of nausea

Timepoint
At recovery (every 10min or having symptom) and 2 and 12 and 24 hours after surgery

Method of measurement
Visual Analogue Scale

2

Description
Score of nausea

Timepoint
At recovery (every 10min or having symptom) and 2 and 12 and 24 hours after surgery

Method of measurement
Visual Analogue Scale

3

Description
Incidence of vomiting
Timepoint
At recovery (every 10min or having symptom) and 2 and 12 and 24 hours after surgery
Method of measurement
scoring system for vomiting

4

Description
Score of vomiting
Timepoint
At recovery (every 10min or having symptom) and 2 and 12 and 24 hours after surgery
Method of measurement
Scoring system for vomiting

5

Description
Score of pain
Timepoint
At recovery (every 10min or having symptom) and 2 and 12 and 24 hours after surgery
Method of measurement
Visual Analogue Scale

6

Description
First time using anti emetic drug
Timepoint
24 hours after entering recovery
Method of measurement
minute

7

Description
Total dose of anti emetic
Timepoint
24 hours after entering recovery
Method of measurement
file

8

Description
Frequency of using anti emetic drug
Timepoint
24 hours after entering recovery
Method of measurement
file

9

Description
Extubation time
Timepoint
After Extubation
Method of measurement
minute

10

Description
Length of stay in recovery
Timepoint
After exiting recovery
Method of measurement
minute

11

Description
Patient satisfaction score
Timepoint
24 hours after entering recovery
Method of measurement
Likert scale

12

Description
Beginning time of using liquid foods
Timepoint
after using liquid foods
Method of measurement
minute

13

Description
Beginning time of using solid foods
Timepoint
after using solid foods
Method of measurement
minute

14

Description
Length of stay in hospital
Timepoint
After exiting hospital
Method of measurement
day

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After receiving 10ml/kg of ringer lactate and pre-oxygenation for patients, the same anesthetic induction was performed including Fentanyl 2mcg / kg, Propofol 2 mg / kg and Atracurium 0.5 to 0.7 mg / kg, midazolam 0.3 to 0.5mcg / kg and the patients underwent mechanical ventilation by mask and ambobag for three minutes. Immediately after intubation, 1 cc of

dexamethasone (4mg) was injected in each nostril.

Category

Prevention

2

Description

Control group: After receiving 10ml/kg of ringer lactate and pre-oxygenation for patients, the same anesthetic induction was performed including Fentanyl 2mcg / kg, Propofol 2 mg / kg and Atracurium 0.5to 0.7mg / kg, midazolam 0.3to 0.5mcg / kg and the patients underwent mechanical ventilation by mask and ambobag for three minutes. Immediately after intubation, 1 ml of normal saline was injected in each nostril.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Hamidreza Shetabi

Street address

Shahid Beheshti Hospital , Motahari St

City

Esfahan

Province

Isfehan

Postal code

8184853543

Phone

+98 31 3236 7001

Email

hamidshetabi@med.mui.ac.ir

2

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Hamidreza Shetabi

Street address

Al-Zahra Therapeutic Training Center, Sofeh Boulevard

City

Esfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 3620 1818

Email

hamidshetabi@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaqayeq Haghjooye Javanmard

Street address

Vice chacellor of research and technology of university isfahan, University of medical sciences, Hezarjerib st

City

Esfahan

Province

Isfehan

Postal code

81746-73461

Phone

+98 31 3792 8134

Email

vcr-office@med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hamidreza Shetabi

Position

associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Al-Zahra Therapeutic Training Center, Sofeh Boulevard

City

Esfahan

Province

Isfehan

Postal code
8174675731
Phone
+98 31 3620 1818
Email
hamidshetabi@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamidreza Shetabi
Position
associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Al-Zahra Therapeutic Training Center, Sofeh Boulevard
City
Esfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 1818
Email
hamidshetabi@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamidreza Shetabi
Position
associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Al-Zahra Therapeutic Training Center, Safeh Boulevard
City
Esfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 1818
Email
hamidshetabi@med.mui.ac.ir

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