

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 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 uncontrolled 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 ; Menstrual period ; Patients with motion sickness and GI problems and history of postoperative nausea and vomiting ; Patients with History of Psychologic 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 uncontrolled 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 Menstrual period Patients with motion sickness and GI problems and history of postoperative nausea and vomiting Patients with History of psychologice 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 unaware 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

Isfahan

##### 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

Isfahan

##### 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

Isfahan

##### 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

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##### Province

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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

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##### Province

Isfahan

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**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**

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**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

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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