

# 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, group 8 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<sup>2</sup>), 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

##### Name

Mohammad Faryadras

##### Name of organization / entity

Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 3428 9706

##### Email address

m.faryadras@umsha.ac.ir

##### 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

##### Street address

shahid Akbar Abadi Hospital, Ferdowsi Station, Molavi st, Tehran

##### City

Tehran

##### Province

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##### Postal code

1168743514

##### Phone

+98 21 6655 2972

##### Email

akbarisene@aiums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Doctor Syed Ali Javad Mousavi

##### Street address

shahid Akbar Abadi Hospital, Ferdowsi Station, Molavi st, Tehran

##### City

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##### Province

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##### Postal code

1449614535

##### Phone

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##### Email

research-m@iums.ac.ir

#### 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

Azadeh Akbari sene

##### Position

Associate Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

shahid Akbar Abadi Hospital, Ferdowsi Station, Molavi st, Tehran

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Azadeh Akbari sene

**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Neda Ardeshiri

**Position**

Resident of Gynecology

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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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