

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of dexamethasone-ondansetrone for the prevention of nausea and vomiting after laparoscopy

#### Protocol summary

2014-02-05, 1392/11/16

#### Summary

Recently most of laparoscopic surgeries especially gynecologic procedures are performed in an outpatient basis and early discharge of these patients without any significant complication is very important. One of the most common causes of late discharge or even admission of ambulatory surgeries is postoperative nausea and vomiting. The aim of this study is to assess the efficacy of antiemetic for prevention of postoperative nausea and vomiting. Following approval from the Local Ethics Committee and receipt of written informed consent, 105 ASA physical status I-II patients who underwent diagnostic laparoscopy will be enrolled into the study in three groups. General anesthesia will be standardized. The patients in group 1 will be receive 8mg Dexamethasone before induction of anesthesia, Group 2 will be receive 4mg Ondansetron IV before the end of surgery and group 3 will be received dexamethasone plus ondansetron as the same doses and ways. Nausea-vomiting will be evaluated with Bellville score and patients will be taken antiemetic (10mg Metoclopramide IV) for scores of 2 or 3. besides, the incidence of Nausea-vomiting, total rescue antiemetic doses and any other complications including pain, agitation and sedation also will be recorded. All data will be statistically analyzed using SPSS v.16.

#### Registrant information

##### Name

Farnaz Moslemi Tabrizi

##### Name of organization / entity

Alzahra hospital, Tabriz university of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1553 9161

##### Email address

moslemif@tbzmed.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Tabriz University of Medical Sciences

#### Expected recruitment start date

2013-03-20, 1391/12/30

#### Expected recruitment end date

2014-03-20, 1392/12/29

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of dexamethasone-ondansetrone for the prevention of nausea and vomiting after laparoscopy

#### Public title

Effect of combined dexamethasone-ondansetrone versus dexamethasone and ondansetrone alone for the prevention of nausea and vomiting after outpatient gynecological diagnostic laparoscopy

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014012511700N3**

Registration date: **2014-02-05, 1392/11/16**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

Inclusion criteria: women with 20-50 years old; women with ASA physical status I and II; patients who have given informed consent  
Exclusion criteria: patients with ASA physical status III or higher; cardiovascular disease; respiratory disease; gastrointestinal disease; hypertension; diabetes; patients who had antiemetic therapy

#### Age

From **20 years** old to **50 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **105**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Vice Chancellor for Research, Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Golgasht Ave, Tabriz

##### City

Tabriz

##### Postal code

#### Approval date

2013-02-18, 1391/11/30

#### Ethics committee reference number

92125

## Health conditions studied

### 1

#### Description of health condition studied

Nausea and Vomiting

#### ICD-10 code

074.6

#### ICD-10 code description

Other complications of spinal and epidural anaesthesia during labour and delivery

## Primary outcomes

### 1

#### Description

Nausea and Vomiting

#### Timepoint

In recovery room and until discharge of Hospital

#### Method of measurement

The intensity of nausea and vomiting with Belville score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Group 1, will receive 8 mg IV Dexamethazone before induction of anesthesia

#### Category

Treatment - Drugs

### 2

#### Description

Group 2 will receive 4 mg IV ondansetron before induction of anesthesia

#### Category

Treatment - Drugs

### 3

#### Description

Group 3 will receive 8 mg Dexamethazone and 4 mg Ondansetron IV before induction of anesthesia

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Alzahra Hospital

##### Full name of responsible person

Dr. Farnaz Moslemi

##### Street address

Alzahra Hospital, South Artesh Ave, Tabriz

##### City

Tabriz

## Sponsors / Funding sources

## 1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Farnaz Moslemi

**Street address**

Alzahra Hospital, South Artesh Ave, Tabriz

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

### Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Farnaz Moslemi

**Position**

Associate Professor of Anesthesiology, Specialist in Anesthesiology

**Other areas of specialty/work**

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### Person responsible for scientific inquiries

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### Person responsible for updating data

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### Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*