

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

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

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

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

Street address

Alzahra Hospital, Artesh Ave, Tabriz

City

Tabriz

Postal code

Phone

+98 41 1553 9161

Fax

+98 984115566449

Email

moslemi_fa@yahoo.com

Web page address

Person responsible for scientific 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

Street address

Alzahra Hospital, Artesh Ave, Tabriz

City

Tabriz

Postal code

Phone

+98 41 1553 9161

Fax

Email

moslemi_fa@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

TTabriz University of MMedical Sciences

Full name of responsible person

Dr.Farnaz Moslemi

Position

Associate Professor of Anesthesiology, Specialist in Anesthesiology

Other areas of specialty/work

Street address

Alzahra Hospital, Artesh Ave, Tabriz

City

Tabriz

Postal code

Phone

+98 41 1553 9161

Fax

+98 41 1556 6449

Email

Moslemi_fa@yahoo.com

Web page address

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