Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Pre-emptive with Preventive Effect of Intravenous Ondansetron on severity of Postoperative Nausea and Vomiting after Diagnostic Gynecologic Laparoscopy

Protocol summary

Summary

Postoperative nausea and vomiting (PONV) remains the most common postoperative complication. The aim of the present study is to compare the antiemetic effect of intravenous ondansetron before the beginning of surgery or at the end of operation for prophylaxis of PONV in patients undergoing diagnostic gynecologic laparoscopy under general anesthesia. Exclusion criteria is history of systemic disease, motion sickness recently taking opioid and corticosteroid. In this randomized blinded clinical trial, 80 patients with ASA class I and aged 20-40 years are randomly allocated into two equal groups. Ondansetron 4mg is administered prior to induction of anesthesia in the study group (n=40), or at the end of surgery in the control group(n=40). Severity of nausea (as measured on a10-cm visual analogue scale), number of emetic episodes, first request to antiemetic, and total dose of antiemetic are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402037013N9**
Registration date: **2014-02-18, 1392/11/29**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-18, 1392/11/29

Registrant information

Name

Simin Atashkhoei

Name of organization / entity

Tabriz University of Medical Siences

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-30, 1392/10/09

Expected recruitment end date

2014-12-29, 1393/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Pre-emptive with Preventive Effect of Intravenous Ondansetron on severity of Postoperative Nausea and Vomiting after Diagnostic Gynecologic Laparoscopy

Public title

Comparison the effect of intravenous ondansetron before or the end of surgery on severity of postoperative nausea and vomiting after diagnostic gynecologic laparoscopy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Women aged 20-40 years; ASA class 1; scheduled for diagnostic gynecologic laparoscopy

Exclusion criteria: vaginal hemorrhage; taking any medication, including corticosteroids , opioids and antiemetics; history of systemic disease(cardiovascular, respiratory, renal ,...); history of motion sickness; history of gastrointestinal disease; pregnancy

Age

From **20 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not 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

Research Vice Chancellor; Daneshgah Street; Tabriz

City

TABRIZ

Postal code

Approval date

2013-12-30, 1392/10/09

Ethics committee reference number

92163

Health conditions studied

1

Description of health condition studied

Complications of medical and surgical care

ICD-10 code

Y83-Y84

ICD-10 code description

Surgical and other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes

1

Description

Intensity of nausea and vomiting

Timepoint

Recavery and at 3, 6,and 24h postoperatively

Method of measurement

Visual analogue scoring 0-10cm(0=non to 10= vomiting more than 2 times)

Secondary outcomes

1

Description

Total dose of antiemeticafter operation

Timepoint

Recovery and during 24h postoperatively

Method of measurement

mg

Intervention groups

1

Description

Iin the control group (n=40), Ondansetron 4mg is administered prior to induction of anesthesia.

Category

Prevention

2

Description

In the study group (n=40) Ondansetron 4mg is administered at the end of surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Dr.Simin Atashkhoyi

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Vice Chancellor of Tabriz University, Medical Sciences
Full name of responsible person
Dr. Rashidi
Street address
Research Vice Chanceller, Tabriz University, Daneshgah Street, Tabriz
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Vice Chancellor of Tabriz University, 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

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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