Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of ondansetron and dexamethasone on reduction of post operative nausea and vomiting (PONV) in laparoscopic cholecystectomy

Protocol summary

Summary

This study compares the effects of dexamethasone and ondansetron in reducing nausea and vomiting after laparoscopic cholecystectomy. In this double blind clinical trial, 90 patients who have undergone laparoscopic cholecystectomy with general anesthesia are randomly assigned into three groups of 30 persons each and are equally placed under total intravenous general anesthesia. Before anesthesia, the patients in the intervention group will receive dexamethasone, 8 mg intravenous or ondansetron 4 mg intravenous and in the control group will receive normal saline 2cc intravenous. Postoperative nausea and vomiting were evaluated in the recovery room and 6 and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201110194093N2**
Registration date: **2011-11-15, 1390/08/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-11-15, 1390/08/24

Registrant information

Name

Masood Entezariasl

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1225 1688

Email address

m.entezari@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ardabil University of Medical Sciences

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-06-19, 1391/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ondansetron and dexamethasone on reduction of post operative nausea and vomiting (PONV) in laparoscopic cholecystectomy

Public title

The effect of ondansetron and dexamethasone on reduction of post operative nausea and vomiting (PONV) in laparoscopic cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Candidate for laparoscopic cholecystectomy, ASA class I-II, age 15-80 years
Exclusion criteria: Gastroesophageal reflux - Severe obesity - difficult airway

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **90**

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
Ardabil University of Medical Sciences

Street address
Daneshgah street, Ardabil

City
Ardabil

Postal code

Approval date
2011-09-08, 1390/06/17

Ethics committee reference number
4/902

Health conditions studied

1

Description of health condition studied
Nausea and vomiting after laparoscopic cholecystectomy

ICD-10 code
K91.0

ICD-10 code description
Vomiting following gastrointestinal surgery

Primary outcomes

1

Description
Nausea after surgery

Timepoint
In the recovery room after surgery-6 and 24 hours after surgery

Method of measurement
Observation and history taking of patients, relatives and nursing staff

2

Description
Vomiting after surgery

Timepoint
In the recovery room after surgery-6 and 24 hours after surgery

Method of measurement
Observation and history taking of patients, relatives and nursing staff

Secondary outcomes

empty

Intervention groups

1

Description
Dexamethasone (8 mg, increased volume to 2 ml) before induction of anesthesia

Category
Prevention

2

Description
Ondansetron(4mg, increased volume to 2 ml) before induction of anesthesia

Category
Prevention

3

Description
Normal Saline, 2 ml, before induction of anesthesia

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital

Full name of responsible person
Masood Entezariasl

Street address

City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Dr Akbar Pirzadeh

Street address
School of Medicine, Ardabil University of Medical Sciences, Ardabil, Iran
City
Ardabil
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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
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Other areas of specialty/work
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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