

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jul 2026

### The effect of ondansetron and metoclopramide on postoperative nausea and vomiting (PONV) in laparoscopic cholecystectomy.

#### Protocol summary

##### Summary

This study compares the effects of metoclopramide 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 metoclopramide, 10 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: **IRCT201111094093N3**

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

2012-03-19, 1390/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of ondansetron and metoclopramide on postoperative nausea and vomiting (PONV) in laparoscopic cholecystectomy.

##### Public title

The effect of ondansetron and metoclopramide on postoperative nausea and vomiting (PONV) in laparoscopic cholecystectomy

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: Candidate for laparoscopic cholecistectomy, 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**

3/902

**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**

Metoclopramide (10 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**

Ardabil University of Medical Sciences

**Full name of responsible person**

Masood Entezariasl

**Position**

Associate Professor of Anesthesiology

**Other areas of specialty/work****Street address**

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**City**

Ardabil

**Postal code****Phone****Fax****Email****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