

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effectiveness of ondansetran and metoclopramide combined with dexamethasone on the prevention of nausea and vomiting after laproscopic cholecystectomy

Protocol summary

Summary

The purpose of this study is to compare the effects of ondansetron with metoclopramide and dexamethasone on the incidence of nausea and vomiting after laparoscopic cholecystectomy. This study is a double blind trial on 100 patients, aged 16-60, with ASA I-II. The patients who have undergone elective laparoscopic cholecystectomy under general anesthesia are randomly assigned to receive an injection of 4mg ondansetron plus 8mg dexamethasone or 10mg metoclopramide plus 8mg dexamethasone 5 minutes before the end of surgery. Incidence of nausea and vomiting are assessed and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201009084715N1**
Registration date: **2010-10-14, 1389/07/22**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-10-14, 1389/07/22

Registrant information

Name

Yosof Mortazavi

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 4142

Email address

y.mortazavi@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Babol University of Medical Sciences

Expected recruitment start date

2010-09-23, 1389/07/01

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

Comparison of the effectiveness of ondansetran and metoclopramide combined with dexamethasone on the prevention of nausea and vomiting after laproscopic cholecystectomy

Public title

Comparison of the effectiveness of ondansetran and metoclopramide combined with dexamethasone on the prevention of nausea and vomiting after laproscopic cholecystectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: undergoing elective cholecystectomy with laparoscopic method Exclusion criteria: past history of post operative nausea and vomiting, motion sickness, obesity

Age

From **16 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Babol University of Medical Sciences

Street address

Babol University of Medical Sciences, Ganjafroz St.

City

Babol

Postal code

Approval date

2010-09-06, 1389/06/15

Ethics committee reference number

1391/30/15/6/1389 زاپ مورخ

Health conditions studied

1

Description of health condition studied

laproscopic cholecystectomy

ICD-10 code

Z90.4

ICD-10 code description

Acquired absence of other parts of digestive tract

Primary outcomes

1

Description

nausea

Timepoint

four hours after the surgery

Method of measurement

Visual scale for nausea

2

Description

Vomiting

Timepoint

four hours after the surgery

Method of measurement

visual scale for Vomiting

Secondary outcomes

empty

Intervention groups

1

Description

Ondansetron, 4mg plus Dexemethasone, 8mg, IV injection, 5 minutes before the end of surgery

Category

Treatment - Drugs

2

Description

Metoclopramide, 10mg plus Dexemethasone, 8mg, IV injection, 5 minutes before the end of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospitals

Full name of responsible person

Street address

Akberaen street, Babol

City

Babol

2

Recruitment center

Name of recruitment center

Shahid Yahyanejad hospital

Full name of responsible person

Street address

Farhang cross, Babol

City

Babol

3

Recruitment center

Name of recruitment center

Ayatollah Rohani hospital

Full name of responsible person

Street address

Keshavarz street, Babol

City
Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

DR Mostafazade

Street address

Babol University of Medical Sciences, Ganjafroz St.,
Babol

City

Babol

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Yosof Mortazavi

Position

Academic staff

Other areas of specialty/work

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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