# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Effect of ondanstron and dexametasone on post operative nausea and vomiting in paients undergoing laparascopic cholecystectomy

## Protocol summary

**Summary**

The purpose of this randomized, double-blind clinical trial without placebo is to compare the effect of ondanstron and dexametasone on nausea and vomiting after laparascopic cystectomy. In this study, 150 patients undergoing laparoscopic cholecystectomy operation between 65-20 years of age who meet the study inclusion and exclusion criteria are randomly assigned in one of the three intervention groups to receive ondansetron or dexamethasone, or combination of them immediately before they receive general anesthesia and the presence or absence of nausea and vomiting in the three groups will be compared.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT201105056392N1**
Registration date: **2011-06-11, 1390/03/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2011-06-11, 1390/03/21

**Registrant information**

**Name**
Hamid Reza Vafaei
**Name of organization / entity**
Kashan University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 36 1555 0026
**Email address**
vafaee_h@kaums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Kashan University of Medical Sciences

**Expected recruitment start date**

2010-08-23, 1389/06/01

**Expected recruitment end date**

2011-08-23, 1390/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Effect of ondanstron and dexametasone on post operative nausea and vomiting in paients undergoing laparascopic cholecystectomy

**Public title**

Effect of ondanstron and dexametasone on post operative nausea and vomiting in paients undergoing laparascopic cholecystectomy

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion criteria: age between 20-65 years old, referring for elective laparascopic cholecystectomy Excluding criteria: Having nausea and/ or vomiting, taking any antiemetic medication within 48 hrs before surgery, having taken H2 blockers, having a history of motion sickness, pregnancy, menstruation, renal disease with high BUN and Cr, receiving any investigational drug within 30 days prior to the surgery, requiring open approach during Laparoscopic approach

**Age**

From **20 years** old to **65 years** old

**Gender**

Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **150**
**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**
Ethics in Medical Research of Kashan University of Medical Sciences
**Street address**
Kashan University of Medical Sciences
**City**
Kashan
**Postal code**
**Approval date**
2011-04-27, 1390/02/07
**Ethics committee reference number**
29/5/1/476 /پ

## Health conditions studied

### 1

**Description of health condition studied**
nausea and vomiting
**ICD-10 code**
K91.0
**ICD-10 code description**
Vomiting following gastrointestinal surgery

## Primary outcomes

### 1

**Description**
nausea and vomiting
**Timepoint**
6 hours and 24 hours after intervention
**Method of measurement**
Questionnaires and observation

## Secondary outcomes

### 1

**Description**
Duration of anesthesia
**Timepoint**
Operation from start to end
**Method of measurement**
Per minute

## Intervention groups

### 1

**Description**
Ondansetron, 4mg, intravenously, immediately before receiving general anesthesia
**Category**
Treatment - Drugs

### 2

**Description**
dexamethasone, 8mg, intravenously, immediately before receiving general anesthesia
**Category**
Treatment - Drugs

### 3

**Description**
Combination of Ondansetron, 4mg, as well as Dexamethasone, intravenously, immediately before receiving general anesthesia
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Kashan Shahid Beheshti Hospital
**Full name of responsible person**
Dr. Hamid Reza Vafaei
**Street address**
Unit 404- Complex Physicians- Amryh Square- Kashan
**City**
Kashan

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Kashan University of Medical Sciences
**Full name of responsible person**
Dr. Gholamali Hamidi
**Street address**

Research- Kashan University of Medical Sciences-5 km polar Ravandi Blvd

**City**
Kashan

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Kashan 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**
Kashan University of Medical Sciences

**Full name of responsible person**
Dr. Hamid Reza Vafaei

**Position**
General Surgery Resident

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Board of General Surgery

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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*