

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of the Effect of Ondansetron, Dexamethasone and Their Combination in Reducing Nausea and Vomiting Following Laparoscopic Cholecystectomy

Protocol summary

Summary

Objective: Comparison of Ondansetron and Dexamethasone effect and also combination of these two drugs effect in prevention of nausea and vomiting caused by laparoscopic cholecystectomy in patients admitted to the Semnan Kowsar hospital. Study design: randomized (random blocks), single-blinded, placebo-uncontrolled, single-center, phase II clinical trials. Inclusion criteria: At least 18 years; patients in ASA Groups (one and two). Exclusion criteria: Gastroesophageal reflux disease; severe obesity; airway problems; pregnancy; lactation; liver or kidney disorders. Sample size, intervention, time of intervention, outcomes studied: 90 patients were admitted to Kowsar hospital, the patients were randomly divided into three groups, with 30 patients in each groups, Group A: 16 mg of dexamethasone was injected intravenously; Group B: 4 mg ondansetron was injected intravenously; group C: 4 mg ondansetron plus 8 mg dexamethasone were injected intravenously. After patient transferring to the operating room bed and primary activities, the anti-nausea drugs were prepared in identical with volume 2ml syringe by a medical student and then immediately administered before the first surgical incision by an anesthesiologist that who will be unaware of the drug. The anesthesia were performed with the same way in all three groups. The patients were extubated and transferred to the recovery room after making proper breathing, furthermore, the patient's nausea and vomiting were checked during 6 and 24 hours after surgery. The patient's recovery period was recorded after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020725732N13**

Registration date: **2017-05-01, 1396/02/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-01, 1396/02/11

Registrant information

Name

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Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

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Recruitment status

Recruitment complete

Funding source

Semnan University of Medical Sciences

Expected recruitment start date

2016-09-13, 1395/06/23

Expected recruitment end date

2017-03-13, 1395/12/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Ondansetron,

Dexamethasone and Their Combination in Reducing Nausea and Vomiting Following Laparoscopic Cholecystectomy

2016-09-13, 1395/06/23

Ethics committee reference number
IR.SEMUMS.REC.1395.93

Public title

Comparison of the Effect of Ondansetron, Dexamethasone and Their Combination in Reducing Nausea and Vomiting Following Laparoscopic Cholecystectomy in patients referred to Semnan Kosar Hospital

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: least 18 years; patients in Group ASA (one and two). Exclusion criteria: Gastroesophageal reflux; severe obesity; airway problem; pregnancy; lactation; liver or kidney disorders; a history of drug addiction; alcoholism; neuromuscular disorders; psychiatric disorders; diabetes, a history of systemic diseases (cardiovascular, respiratory and hypertension).

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Postal code

3514799442

Approval date

Health conditions studied

1

Description of health condition studied

Nausea and vomiting

ICD-10 code

R11

ICD-10 code description

Nausea and vomiting

Primary outcomes

1

Description

Nausea

Timepoint

In the recovery room, 6 and 24 hours after surgery.

Method of measurement

View and visit (registered in the check list)

2

Description

Vomit

Timepoint

In the recovery room, 6 and 24 hours after surgery.

Method of measurement

View and visit (registered in the check list)

3

Description

Recovery time

Timepoint

After laparoscopic cholecystectomy (from time of arrival to the recovery room)

Method of measurement

In minutes

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: 30 cases of patients were injected 16 mg of dexamethasone intravenously based on a simple random sampling. Injection was performed by an anesthesiologist who will be unaware of the drugs type before the first surgery incision immediately. The anesthesia were performed with the same way in all three groups. Furthermore, the patient's nausea and vomiting were checked during 6 and 24 hours after

surgery. The patient's recovery period was recorded after surgery.

Category

Treatment - Drugs

2**Description**

Intervention 2: 30 cases of patients were injected 4 mg of ondansetron intravenously based on a simple random sampling. Injection was performed by an anesthesiologist who will be unaware of the drugs type before the first surgery incision immediately. The anesthesia were performed with the same way in all three groups. Furthermore, the patient's nausea and vomiting were checked during 6 and 24 hours after surgery. The patient's recovery period was recorded after surgery.

Category

Treatment - Drugs

3**Description**

Intervention 3: 30 cases of patients were injected 4 mg of ondansetron plus 8 mg of dexamethasone intravenously based on a simple random sampling. Injection was performed by an anesthesiologist who will be unaware of the drugs type before the first surgery incision immediately. The anesthesia were performed with the same way in all three groups. Furthermore, the patient's nausea and vomiting were checked during 6 and 24 hours after surgery. The patient's recovery period was recorded after surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kosar Hospital, Semnan University of Medical Sciences

Full name of responsible person

Babak Hosein Zadeh

Street address

Kosar Hospital, Street Amin, Semnan

City

Semnan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Semnan University of Medical Sciences

Full name of responsible person

Ali Rashidy-Pour

Street address

Semnan University of Medical Sciences, Deputy of Research and Technology, Basij Blvd, Semnan

City

Semnan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

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Position

Anesthesiologist

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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