Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 antinausea 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

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

Phone

+98 23 3345 1336

Email address

are20935@semums.ac.ir

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

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
2016-09-13, 1395/06/23
Ethics committee reference number
IR.SEMUMS.REC.1395.93

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

Babak Hosein Zadeh

Position

Anesthesiologist

Other areas of specialty/work

Street address

Semnan University of Medical Sciences, Blvd Basij, Semnan

City

Semnan

Postal code

3514799442

Phone

+98 23 3345 1336

Fax

+98 23 3344 8999

Email

are20935@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Babak Hosein Zadeh

Position

Anesthesiologist

Other areas of specialty/work

Street address

Semnan University of Medical Sciences, Blvd Basij,

Semnan

City
Semnan

Postal code
3514799442

Phone
+98 23 3345 1336

Fax
+98 23 3344 8999

Email
are20935@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
Babak Hosein Zadeh

Position
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Other areas of specialty/work

Street address
Semnan University of Medical Sciences, Blvd Basij, Semnan

City
Semnan

Postal code
3514799442

Phone
+98 23 3345 1336

Fax
+98 23 3344 8999

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