Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effects of Preoperative Ondansetron and Clonazepam on Postoperative Nausea and Vomiting after Laparoscopic Cholecystectomy; A Randomized Double-Blind, Placebo Controlled Trial

Protocol summary

Study aim

The aim of the current study is to compare the efficacy of ondansetron and clonazepam in reducing the incidence and severity of PONV and postoperative pain in patients undergoing LC.

Design

In this research, 90 eligible patients referring to Shahid Faghihi hospital were chosen purposefully and were randomly divided into 3 groups of first and second interventions and control. Groups allocation were concealed by assigning a unique code to each participants.

Settings and conduct

Shahid Faghihi hospital, a tertiary healthcare center affiliated with Shiraz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients scheduled for elective LC, having an American Society of Anesthesiologists (ASA) physical status of I or II, between 18 and 65 years of age. Exclusion criteria: patients with body mass index (BMI) more than 30 kg/m2, history of previous severe PONV, history of motion sickness, significant gastrointestinal problems, recent antiemetic drugs consumption, smokers, impaired kidney or liver functions and menstruating, pregnant or lactating females, migraine or cluster headaches, mental retardation or psychiatric disorder and those with chronic alcohol consumption.

Intervention groups

First study group receive 2 mg of oral clonazepam and intravenous injection of placebo 15-minute prior to induction of anesthesia Second group receive 4 mg intravenous injection of ondansetron and oral tablets of placebo in the same time window Control group receive oral and intravenous injection of placebo accordingly

Main outcome variables

Normal vaginal delivery (NVD) percentage

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090912002445N6**
Registration date: **2018-01-22, 1396/11/02**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-22, 1396/11/02**
Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Fariborz Ghaffarpasand

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 3647 4259

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ghafarf@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effects of Preoperative Ondansetron and Clonazepam on Postoperative Nausea and Vomiting after Laparoscopic Cholecystectomy; A Randomized Double-Blind, Placebo Controlled Trial

Public title
Effects of Ondansetron and Clonazepam on Nausea and Vomiting after Laparoscopic Cholecystectomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
between 18 and 65 years of age. Having American Society of Anesthesiologists (ASA) physical status of I or II

Exclusion criteria:
Patients with body mass index (BMI) more than 30 kg/m2 history of previous severe Post-Operative Nausea and Vomiting (PONV) history of motion sickness significant gastrointestinal problems recent antiemetic drugs consumption smokers impaired kidney or liver functions and menstruating pregnant or lactating females migraine or cluster headaches mental retardation psychiatric disorder chronic alcohol consumption

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **90**
Actual sample size reached: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The included patients were randomly assigned to 3 study groups using a computer-based random digit generator utilizing the admission numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
All the patients and physicians administrating the medications will blinded toward the intervention.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Medical Ethics Committee of Shiraz University of Medical Sciences

Street address
Zand Avenue

City
Shiraz

Province
Fars

Postal code
71973–11351

Approval date
2015-11-03, 1394/08/12

Ethics committee reference number
IR.SUMS.MED.REC.1394.321

Health conditions studied

1

Description of health condition studied
Laparoscopic cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Nausea`

Timepoint
1, 3, 6, 12 and 24 hours after the operation

Method of measurement
10-measure visual analogue scale (VAS)

2

Description
Severity of pain

Timepoint
1, 3, 6, 12 and 24 hours after the operation

Method of measurement
10-measure visual analogue scale (VAS)

3

Description
Vomiting

Timepoint
First 12 hours after the operation

Method of measurement
Record of vomiting incidence

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 2 mg of oral clonazepam (Sobhan Darou Inc., rasht, Iran) and intravenous injection of placebo 15-minute prior to induction of anesthesia.
Category
Treatment - Drugs

2

Description
Intervention group: 4 mg intravenous injection of ondansetron (Alborz Darou Inc, Tehran, Iran) and oral tablets of placebo
Category
Treatment - Drugs

3

Description
Control group: oral and intravenous injection of placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Faghihi hospital
Full name of responsible person
Reza Raeesi Estabragh
Street address
Zand Avenue, Shiraz, Iran.
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7194815644
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Abdolkhalegh Keshavarzi
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Shiraz University of Medical Sciences, Zand Avenue
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Phone
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Email
keshavarzi.ak@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Reza Raeesi Estabragh
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available