

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+98 71 3647 4259

Email address

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.

City

Shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3647 4270

Email

r.raeesi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abdolkhalegh Keshavarzi

Street address

Shiraz University of Medical Sciences, Zand Avenue

City

Shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3212 2204

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

Street address

Nemazi Hospital, Zand Avenue, Shiraz, Iran.

City

Shiraz

Province

Fars

Postal code

7194815644

Phone

+98 71 3647 4270

Fax

+98 71 3647 4270

Email

r.raeesi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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Person responsible for updating data

Contact

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Email

r.raeesi@yahoo.com

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