Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison between effects of oral Lorazepam with placebo in decreasing nausea and vomiting after laparoscopic cholecystectomy under general anesthesia

Protocol summary

Summary

Aim: The purpose of this study was to compare the effect of oral lorazepam with placebo in reducing nausea and vomiting in patients undergoing laparoscopic cholecystectomy after general anesthesia. This study design with simple random sampling and double blind on 76 patients with ASA I- II undergoing laparoscopic cholecystectomy will be done .After the patients were selected based on inclusion: Age: 20-60 years, B MI<30, Duration of surgery <1 hour, ASA: I- II and exclusion criteria: Hemodynamic effect after administration of lorazepam, Anti emetic medication before surgery , Systolic blood pressure less than 90 mm Hg or greater than 160 mm Hg, History of drug abuse and tricyclic antidepressants ; were randomly placed in two groups . One milligram lorazepam pill with 10 mL of water will be given in treatment group and the control group given a placebo pill, 60 minutes before surgery. Primary outcomes: Post operative nausea and vomiting. Secondary outcome: Satisfaction of patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014051917742N2**
Registration date: **2016-06-12, 1395/03/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-06-12, 1395/03/23

Registrant information

Name

Fatemeh Javaherforoosh Zadeh

Name of organization / entity

Ahvaz Joundishapoor University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1391 9315

Email address

javaherforosh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research o f Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-12-22, 1394/10/01

Expected recruitment end date

2016-06-22, 1395/04/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between effects of oral Lorazepam with placebo in decreasing nausea and vomiting after laparoscopic cholecystectomy under general anesthesia

Public title

Lorazepam effect on reducing nausea and vomiting

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria :Age: 20-60 years, B MI<30, Duration of surgery <1 hour, ASA: I- II Exclusion criteria: Hemodynamic effect after administration of lorazepam, Anti emetic medication before surgery , Systolic blood

pressure less than 90 mmHg or greater than 160 mmHg, History of drug abuse and tricyclic antidepressants

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **76**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address
Golestan street,Ahvaz

City
Ahvaz

Postal code

Approval date
2015-05-22, 1394/03/01

Ethics committee reference number
B-9370 :کد ثبت , ajums.REC.1394.3

Health conditions studied

1

Description of health condition studied
Hyperemesis gravidarum

ICD-10 code
O21.1

ICD-10 code description
Hyperemesis gravidarum with metabolic disturbance

Primary outcomes

1

Description
nausea

Timepoint
0,6,24 hiurs after surgery

Method of measurement
visual analog scale

2

Description
vomiting

Timepoint
0,6,24 hiurs after surgery

Method of measurement
visual analog scale

Secondary outcomes

1

Description
Satisfaction

Timepoint
0,6,24 hours after surgery

Method of measurement
Likert scale

Intervention groups

1

Description
Administration of lorazepam 1 mg 60 minutes before surgery in treatment group

Category
Prevention

2

Description
Administration of placebo tab 60 minutes before surgery in control group

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Razi Hospital

Full name of responsible person
Dr Fatemeh Javaherforoosh Zadeh

Street address

City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr Nader Saki
Street address
Imam Khomini Hospital-Azadegan street
City
Ahvaz
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 Ahvaz Jundishapur 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
Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
Full name of responsible person
Dr Fatemeh Javaherforoosh Zadeh
Position
Associate professor of Anesthesia
Other areas of specialty/work
Street address
Imam Khomini Hospital,Azadegan street
City
Ahvaz
Postal code
Phone
+98 61 3333 3050
Fax
Email
f_javaherforoosh@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
Full name of responsible person
Dr Fatemeh Javaherforoosh Zadeh
Position
Associate professor of Anesthesia
Other areas of specialty/work
Street address
Imam Khomini Hospital,Azadegan street
City
Ahvaz
Postal code
Phone
+98 61 3333 3050
Fax
Email
f_javaherforoosh@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran
Full name of responsible person
Dr Fatemeh Javaherforoosh Zadeh
Position
Associate professor of Anesthesia
Other areas of specialty/work
Street address
Imam Khomini Hospital,Azadegan street
City
Ahvaz
Postal code
Phone
Fax
Email
f_ javaherforoosh@yahoo.com
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