

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 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 hours after surgery

#### Method of measurement

visual analog scale

### 2

#### Description

vomiting

#### Timepoint

0,6,24 hours 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**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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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*