

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparative evaluation of low-dose pregabalin versus placebo on pain relief after surgery in Laparoscopic Cholecystectomy patients

#### Protocol summary

##### Summary

The purpose of this study is Comparison of low dose Pregabalin versus placebo on postoperative pain reduction in Laparoscopic Cholecystectomy patients. In this randomized, double blind clinical trial, a number of 172 patients, 20 - 60 years old inclusion criteria: candidate for elective laparoscopic Cholecystectomy; lack of severe systemic and mental disease; consent to take part in the study and exclusion criteria: history of drug allergy; opiate use; sedative use enrolled in study. They are randomly divided into two groups: Pregabalin and placebo. Thirty min before surgery study group takes 150 milligram Pregabalin orally and the control group received placebo orally with a glass of water. Laparoscopic Cholecystectomy is performed by one surgeon with same surgical technique under general anesthesia at the end of surgery after transferring to the ward, four, six and 24 hours after surgery pain measure and record by collaborator who does not know about grouping by using a visual index (Visual Analogue Scale) and analyzed

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201312041617N8**

Registration date: **2014-06-15, 1393/03/25**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-06-15, 1393/03/25

##### Registrant information

##### Name

Mansour Choubsaz

##### Name of organization / entity

Imam Reza Hospital

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 1724 6708

##### Email address

mchoubsaz@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Kermanshah University of Medical Sciences Kermanshah

##### Expected recruitment start date

2014-01-21, 1392/11/01

##### Expected recruitment end date

2015-01-21, 1393/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative evaluation of low-dose pregabalin versus placebo on pain relief after surgery in Laparoscopic Cholecystectomy patients

##### Public title

Comparison of low-dose pregabalin versus placebo on pain relief after surgery in Laparoscopic Cholecystectomy patients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: candidate for elective laparoscopic Cholecystectomy; lack of severe systemic and mental disease; consent to participate in the study Exclusion criteria: history of drug allergy; opiate use; sedative use

##### Age

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **172**

**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**

Ethic Committee of Kermanshah University of Medical Sciences

**Street address**

Ethic Committee of Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard

**City**

Kermanshah

**Postal code**

**Approval date**

2013-11-06, 1392/08/15

**Ethics committee reference number**

33822

**Health conditions studied**

1

**Description of health condition studied**

Epigastric pain

**ICD-10 code**

R10.1

**ICD-10 code description**

Pain localized to upper abdomen

**Primary outcomes**

1

**Description**

pain

**Timepoint**

4,6,24 hours

**Method of measurement**

Visual analogue score

**Secondary outcomes**

empty

**Intervention groups**

1

**Description**

Pregabalin 150 mg oral tablet with a glass of water one hours before surgery

**Category**

Prevention

2

**Description**

Placebo oral tablet with a glass of water one hour before surgery

**Category**

Prevention

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Farid Najafi

**Street address**

Kermanshah University of Medical Sciences , Shahid Beheshti Boulevard

**City**

Kermanshah

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Nikbakhat

**Street address**

Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard

**City**

Kermanshah

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Imam Reza Hospital

**Full name of responsible person**

Somayeh Mohammadi

**Position**

Resident of Anesthesiology

**Other areas of specialty/work****Street address**

Departement of Anesthesia and Intensive care, Imam Reza Hospital

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**Postal code**

6718938179

**Phone**

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mchoobsaz@kums.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Imam Reza Hospital

**Full name of responsible person**

Mansour Choubsaz

**Position**

Anesthesiologist, Assistant Professor

**Other areas of specialty/work****Street address**

Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Imam Reza Hospital

**Full name of responsible person**

Mansour Choubsaz

**Position**

Anesthesiologist, Assistant Professor

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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*