

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

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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

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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