

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparison of the effect of single preoperative dose of Gabapentin and Pregabalin on postoperative pain after laparoscopic cholecystectomy in patients

Protocol summary

Study aim

Comparison of the effect of single preoperative dose of Gabapentin and Pregabalin on postoperative pain after laparoscopic cholecystectomy in patients

Design

Clinical trial with parallel control group, randomized, Control with placebo, single center trial, Sample size 75 people.

Settings and conduct

Kowsar Hospital. Patients are divided into three groups: placebo (control group), gabapentin consumption (intervention group 1), and pregabalin consumption (intervention group 2) and enter the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 25 to 60 years; Candidates for elective laparoscopic cholecystectomy. Exclusion criteria: Drug addiction; Liver or kidney disorders; Taking anticonvulsants or antidepressants; Breastfeeding.

Intervention groups

Intervention group 2: One hour before the operation, the patient is given 600 mg of gabapentin capsules with some water. Paracetamol ampules are used to relieve postoperative pain in patients. Intervention group 2: One hour before the operation, the patient is given 150 mg of pregabalin capsule with some water. Paracetamol ampules are used to relieve postoperative pain in patients. Control group: One hour before the operation, the patient is given a placebo (domperidone 10 mg capsule) with a little water. Paracetamol ampules are used to relieve postoperative pain in patients.

Main outcome variables

Pain; Frequent demand for narcotic housing; Duration of surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N67**

Registration date: **2021-05-24, 1400/03/03**

Registration timing: **prospective**

Last update: **2021-05-24, 1400/03/03**

Update count: **0**

Registration date

2021-05-24, 1400/03/03

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

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are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-05, 1400/03/15

Expected recruitment end date

2021-12-06, 1400/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of single preoperative dose of Gabapentin and Pregabalin on postoperative pain after laparoscopic cholecystectomy in patients

Public title

Comparison of the effect of single preoperative dose of Gabapentin and Pregabalin on postoperative pain after laparoscopic cholecystectomy in patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 25 to 60 years Candidates for elective laparoscopic cholecystectomy

Exclusion criteria:

Drug addiction Liver or kidney disorders Taking anticonvulsants or antidepressants Breastfeeding

Age

From **25 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are allocated randomly with simple sequential allocation in one of the three study groups by help of sealed envelope and receive the intervention of the same group. The unit of randomization is patient. Sealed envelopes are delivered to expert. With each patient's visit, one of the envelopes is randomly selected by the patients and determines the study group. The stratification approach is not used.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij Blvd, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2021-04-27, 1400/02/07

Ethics committee reference number

IR.SEMUMS.REC.1400.012

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Pain

Timepoint

At 1, 2, 6, 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Frequent demand for narcotic housing

Timepoint

Number of times the patient requests after the operation

Method of measurement

Questionnaire

3

Description

Duration of surgery

Timepoint

From the beginning of the surgery to its end

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 2: One hour before the operation, the patient is given 600 mg of gabapentin capsules with

some water. Paracetamol ampules are used to relieve postoperative pain in patients.

Category

Treatment - Drugs

2**Description**

Intervention group 2: One hour before the operation, the patient is given 150 mg of pregabalin capsule with some water. Paracetamol ampules are used to relieve postoperative pain in patients.

Category

Treatment - Drugs

3**Description**

Control group: One hour before the operation, the patient is given a placebo (domperidone 10 mg capsule) with a little water. Paracetamol ampules are used to relieve postoperative pain in patients.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Kowsar Hospital

Full name of responsible person

Setareh Soltany

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Street Amin, Semnan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Semnan University of Medical Sciences

Full name of responsible person

Parviz Kokhaei

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Semnan 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**

Semnan University of Medical Sciences

Full name of responsible person

Setareh Soltany

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Elahe Pasand Masoumi

Position

Student

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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

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available