Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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+98 23 3345 1336

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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

Street address

Street Amin, Semnan

City

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3519899951

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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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Full name of responsible person

Setareh Soltany

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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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

Latest degree

Medical doctor

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General Practitioner

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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