Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Evaluation of the effect of preoperative administration of pregabalin in comparison with co-administration of pregabalin and celecoxib on postoperative pain of laparoscopic cholecystectomy under general anesthesia

Protocol summary

Study aim
Determining the effect of preoperative single-dose pregabalin in comparison with celecoxib on pain relief and also reducing the average morphine use and its complications after laparoscopic cholecystectomy under general anesthesia

Design
A controlled, double-blind, randomized clinical trial on 60 patients

Settings and conduct
Place of study performance: Kashani Hospital, Shahrekord city; Study population: acute and chronic cholecystitis patients candidate for laparoscopic cystectomy under general anesthesia; Type of blinding: with coded sealed pockets; Method of blinding: coding was done by one of the colleagues of the study and nurses and patients were blinded to drugs

Participants/Inclusion and exclusion criteria
Inclusion criteria: Ultrasonographic results confirm the presence of gallstones, symptomatic gallstone disease, candidate for elective laparoscopic cholecystectomy, ASA class 1 and 2, age between 20 to 65 years, and consent to participate in the study. Non-inclusion criteria: History of diseases affecting vital signs including heart failure, lung, confirmed malignancy, people older than 65 years, history of drug addiction, need for open cholecystectomy, people with contraindications to anesthesia or opioids

Intervention groups
Intervention Group 1: Administration of only pregabalin; Intervention Group2: Administration of pregabalin with celecoxib; Control group: receiving placebo.

Main outcome variables
Postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210309050652N1**
Registration date: **2023-07-23, 1402/05/01**
Registration timing: **retrospective**

Last update: **2023-07-23, 1402/05/01**
Update count: **0**

Registration date
2023-07-23, 1402/05/01

Registrant information

Name
Ali Sadeghian

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 38 3225 3752

Email address
dr.sadeghian@outlook.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-11-27, 1400/09/06

Expected recruitment end date
2022-01-26, 1400/11/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effect of preoperative administration of pregabalin in comparison with co-administration of pregabalin and celecoxib on postoperative pain of laparoscopic cholecystectomy under general anesthesia

Public title
The effect of pregabalin on postoperative pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Existence of ultrasonographic results confirming the presence of gallstones Symptomatic gallstone disease Candidate for elective surgery for laparoscopic cholecystectomy ASA Class 1 and 2 Age between 20 and 65 years Satisfaction to participate in the study

Exclusion criteria:
Dissatisfaction with participating in the project History of diseases affecting vital signs including heart and lung failure Confirmed malignancy Need an open cholecystectomy People older than 65 years History of Addiction Occurrence of unwanted complications during the operation People with contraindications to anesthesia or opioids (patients with known hypersensitivity to the compounds of various anesthetics) Patients with inability to answer visual pain ruler questions

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated to three groups: A(control), B (only pregabalin) and C (combination of pregabalin and celecoxib), by block randomization with block size of 6. In each block, 2 patients of each group will be exist. The order of blocks will be determined randomly in A or B or C groups and subjects will be allocated sequentially in order of admission. The random allocation rule method was used for the determination of sequences using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the letter envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes of the letter will be opened in order and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients receive drugs (interventions or control groups) in closed pockets which are coded and patients are not aware of their contents. Coding will be done by one of the colleagues of the study and the evaluator nurse will be blind for the type of drugs.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee of Shahrekord University of Medical Sciences

Street address
Shahrekord University of Medical Sciences; Rahbar Boulevard

City
Shahrekord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8818634141

Approval date
2021-10-26, 1400/08/04

Ethics committee reference number
IR.SKUMS.REC.1400.179

Health conditions studied

1

Description of health condition studied
Acute Postoperative Pain

ICD-10 code
K81.0

ICD-10 code description
Acute cholecystitis

Primary outcomes

1

Description
Patients' pain score based on visual and descriptive numerical pain questionnaire

Timepoint

Measurement of patients' pain, immediately after waking up in recovery, two and four hours after surgery

Method of measurement

Visual Analog Scale questionnaire

Secondary outcomes

1

Description

The need for Narcotic Analgesics after surgery

Timepoint

Immediately after waking up in recovery, two to four hours after surgery

Method of measurement

Mg Morphin

2

Description

Hemodynamic symptoms

Timepoint

Immediately after waking up in recovery, two to four hours after surgery

Method of measurement

By measuring heart rate, pulse oximetry, respiratory rate, using blood pressure device

Intervention groups

1

Description

Intervention group: Patients receiving pregabalin (capsule, 150 mg, product by Sobhan company, one time, oral, as single dose 2 hours before starting surgery) with celecoxib (capsule, 200 mg, product by Amin company, one time, oral, as single dose 2 hours before starting surgery)

Category

Prevention

2

Description

Intervention group: Patients receiving only pregabalin (capsule, 150 mg, product by Sobhan company, one time, oral, as single dose 2 hours before starting surgery)

Category

Prevention

3

Description

Control group: They receive placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashani Hospital, Shahrekord

Full name of responsible person

Ali Sadeghian

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Rahbar Bolvar, Shahrekord

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

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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

Shahre-kord 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
Shahre-kord University of Medical Sciences

Full name of responsible person
Hossein Madineh

Position
Associated Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The individual data of the study participants are considered and all the data can potentially be shared after the individuals are not identified.

When the data will become available and for how long
October 2022

To whom data/document is available
Notification is allowed

Under which criteria data/document could be used
Notification is allowed

From where data/document is obtainable
Notification is allowed

What processes are involved for a request to access data/document
It does not have a specific process

Comments
does not have