Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Single Prophylactic Dose of Pregabalin on Pain Management and Opioids After Cholecystectomyin Patients Referred to Bo Ali Hospital in Tehran

Protocol summary

Study aim

The Effect of Single Prophylactic Dose of Pregabalin on Pain Management and Opioids After Cholecystectomyin Patients Referred to Bo Ali Hospital in Tehran

Design

The current study is a randomized clinical trial (blocks of four), double-blind (participants and results analyzer), with parallel groups and phase 2-3, and will be conducted with the participation of 80 patients who are candidates for laparoscopic cholesystemectomy surgery.

Settings and conduct

This randomized and double-blind trial study will be conducted with the participation of 80 patients who are candidates for laparoscopic cholecystectomy surgery; Pregabalin tablets will be given to patients in the intervention group before surgery, and placebo will be given to the patients in the intervention group, and the pain intensity will be compared between them. The participants and the data analyst will be blinded during the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: candidates for laparoscopic cholecystectomy, class I and II according to ASA and consent to participate in the study, and exclusion criteria include: sensitivity to pregabalin, conversion of surgery from laparoscopic to open surgery, and body mass index. There will be more than 40.

Intervention groups

In this study, a randomized and double-blind clinical trial with the participation of 80 patients (intervention group = control group = 40 people) candidates for laparoscopic cholecystectomy, pain intensity between the group receiving pregabalin (300 mg one hour before the start of anesthesia) with The group that does not receive medicine (placebo group: receiving a pill of the same shape and color as pregabalin) will be compared.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230502058057N1**
Registration date: **2023-10-18, 1402/07/26**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-18, 1402/07/26**
Update count: **0**

Registration date

2023-10-18, 1402/07/26

Registrant information

Name

Bahram Davoudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3344 0409

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bahram.davoudi75@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-11, 1402/07/19

Expected recruitment end date

2024-01-04, 1402/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of Single Prophylactic Dose of Pregabalin on Pain Management and Opioids After Cholecystectomyin Patients Referred to Bo Ali Hospital in Tehran

Public title
Effect of a single prophylactic dose of pregabalin on pain management and opioid requirement after cerebrocystectomy

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Laparoscopic cholecystectomy surgery candidate Class I and II according to ASA Consent to participate in the study
Exclusion criteria:
Hypersensitivity to pregabalin Converting surgery from laparoscopy to open surgery Body mass index greater than 40

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, with a sample size of 80, we use the patients using the block permutation randomization method, which is used in this method to balance the number of allocated samples, and with 4 people in each block. We assemble the possible blocks as follows. block 1:BBAA and block 2:AABB and block 3:ABAB and block 4:BABA and block 5:ABBA and block6:BAAB we need 20 blocks for 80 people, these blocks are random in the software environment (version 2.0 (RandomAlloc.exe)) allocation software will be defined so that the number of 20 blocks of 4 will be defined in this software, this software is capable of generating a random sequence using the block method, then we choose from numbers one to six; For example, if number 6 is chosen as the first block and number 2 as the second block, the people who enter the study will be given BAABAABB in order from left to right, and finally to two intervention groups (group A) and group Control (group B) were divided.

Blinding (investigator's opinion)
Double blinded

Blinding description
The thesis results analyst who analyzed the expected outcome and also the participants remained unaware of the type of procedure performed and were blind during the study; Therefore, this study was conducted in a double-blind manner.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Tehran Islamic Azad University Of Medical Sciences
Street address
No 2, mojahed street, mojahedin eslam ave.,shohada sq.,District 12, tehran
City
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Province
Tehran
Postal code
1156837358

Approval date
2023-02-20, 1401/12/01

Ethics committee reference number
IR.IAU.TMU.REC.1401.372

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
G89.11

ICD-10 code description
Acute pain due to trauma

Primary outcomes

1

Description
Pain

Timepoint
Once every hour for six hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Pregabalin 300 mg tablets will be taken orally with a glass of water one hour before surgery, and pain intensity will be measured using the VAS instrument for six hours after surgery (once every hour).
Category
Prevention

2

Description
Control group: PPlacebo tablets (same color and size as pregabalin tablets) will be taken orally with a glass of water one hour before surgery, and pain intensity will be measured using a VAS tool for six hours after surgery (once every hour).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Booali hospital
Full name of responsible person
Dr dehghan manshadi
Street address
Booali hospital,enghelab street,tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
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
Islamic Azad University
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
Islamic Azad University
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Position
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available