

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

The Effect of Single Prophylactic Dose of Pregabalin on Pain Management and Opioids After Cholecystectomy in 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 Cholecystectomy in 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 cholecystectomy 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

Email address

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 Cholecystectomy in 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

Tehran

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

City

Tehran

Province

Tehran

Postal code

1156837379

Phone

+98 21 3344 0405

Email

bahram.davoudi75@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Giti Dehghan Manshadi

Street address

Booali hospital,enghelab street,tehran

City

Tehran

Province

Tehran

Postal code

bahram.davoudi75@gma

Phone

+98 21 3344 0409

Email

bahram.davoudi75@gmail.com

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

Full name of responsible person

Bahram Davoudi

Position

General medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No. 2 , Mojahed St., Mojahedin Eslam Ave., Tehran
Town

City

Tehran

Province

Tehran

Postal code

5981764863

Phone

+98 21 3344 0409

Fax

Email

bahram.davoudi75@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Bahram Davoudi

Position

General medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No. 2 , Mojahed St., Mojahedin Eslam Ave., Tehran
Town

City

Tehran

Province

Tehran

Postal code

5981764863

Phone

+98 21 3344 0409

Fax**Email**

bahram.davoudi75@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Bahram Davoudi

Position

General medicine Student

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

No. 2 , Mojahed St., Mojahedin Eslam Ave., Tehran
Town

City

Tehran

Province

Tehran

Postal code

5981764863

Phone

+98 21 3344 0409

Fax**Email**

bahram.davoudi75@gmail.com

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