Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of pregabalin-paracetamol on shoulder pain in patients after laparoscopic cholecystectomy, Double-blind controlled randomized trial

Protocol summary

Study aim
Determination of the effect of pregabalin-paracetamol on shoulder pain in patients after laparoscopic cholecystectomy

Design
double-blind randomized clinical trial, phase 3 on 90 patients, web-based randomization software was used for randomization.

Settings and conduct
The present study will be performed in the field of pain relief in 90 patients aged 20-60 years who are candidates for laparoscopic cholecystectomy in Imam Ali Hospital of North Khorasan University of Medical Sciences. Patients are randomly assigned to the three groups (two Intervention groups and placebo) using a web-based system.Evaluation of shoulder pain by visual analogue scale pain gauges in time intervals: recovery, 6, 12, 18 and 24 hours after surgery. To perform blinding, patients, surgeons, and individuals performing pain assessments at various intervals will be blinded to the groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 20 to 60 years, ASA physical status I-II, No drug addiction, No disease with chronic pain, No hypersensitivity to Pregabalin and Paracetamol, No history of disease and surgery in the shoulder and chest area Exclusion criteria: Conversion of laparoscopic surgery to laparotomy, any complication that increases postoperative pain

Intervention groups
The first group: Administration One hour before surgery, a single dose of pregabalin 300 mg orally. And 30 minutes before the end of surgery Paracetamol 1 gr per 100 cc of normal saline 0.9% diluted are given as an infusion. Also they will receive 1 gr Paracetamol per 100 cc N/S 0.9% diluted as an infusion per 6 to 24 hours after surgery The second group: Administration a single dose of pregabalin 300 mg orally, One hour before surgery placebo group: Administration of placebo, One hour before surgery

Main outcome variables
Post Operative Pain

General information

Reason for update

Acronym
تاثیر پرگابالین-پاراستامول بر درد شانه

IRCT registration information
IRCT registration number: **IRCT20141001019359N11**
Registration date: **2022-01-09, 1400/10/19**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-09, 1400/10/19**
Update count: **0**

Registration date
2022-01-09, 1400/10/19

Registrant information

Name
Hossein Zeraati

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of pregabalin-paracetamol on shoulder pain in patients after laparoscopic cholecystectomy, Double-blind controlled randomized trial

Public title
Pregabalin and Paracetamol effect on pain after Laparoscopic cholecystectomy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
20 to 60 years ASA physical status I-II No drug addiction No disease with chronic pain No hypersensitivity to Pregabalin and Paracetamol No history of disease and surgery in the shoulder and chest area and abdominal surgery
Exclusion criteria:
Conversion of laparoscopic surgery to laparotomy any complication that increases postoperative pain
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling in this study will be that first in order to enter the study patients will be in the form of non-random sampling of the type "available" and then divide them into three intervention groups by randomly assigned blocking using a web-based system. Random blocking at www.randomization.com will be done in 15 blocks of 6. So that in each block, there are 2 people in the first group (A), two people in the second group (B) and two people in the third group (C). After a random sequence was identified in all blocks, cards were written by writing C, B, and A to indicate which group each patient was assigned to, and by someone other than the research team from 1 to 90 in all blocks, respectively. They are numbered and these cards are placed in sealed non-transparent envelopes, respectively. Then, in order to hide the random allocation, when the patient visits, the opaque sealed envelope will be opened and then one by one, it will be determined for each sample of the relevant group.
Blinding (investigator's opinion)
Double blinded
Blinding description
None of the participants in the study will be aware of the randomization list and also to apply allocation concealment randomization, the groups are placed in closed envelopes in the admission section and eligible individuals who enter the study are included respectively.Therefore, the study was double-blind so that patients and outcome evaluation specialist are unaware of the allocation status of the three groups to the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of North Khorasan University of Medical Sciences
Street address
Vice Chancellor for Research of North Khorasan University of Medical Sciences, Bojnurd
City
Bojnurd
Province
North Khorasan
Postal code
9416678894
Approval date
2021-05-02, 1400/02/12
Ethics committee reference number
IR.NKUMS.REC.1400.019

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
R52.0
ICD-10 code description
Pain, not elsewhere classified

Primary outcomes

1

Description
Post Operative Pain
Timepoint
Assay of pain at 0, 2, 4, 6, 8, 12 and 24 hours after surgery

Method of measurement
Visual Analog Score (VAS) Form of pain

2

Description
Pethedine/Morphine Consumption
Timepoint
First 24 hours after surgery
Method of measurement
Pethidine/Morphine consumption doses

Secondary outcomes

1

Description
Time of surgery
Timepoint
From induction of anesthesia time to extubation
Method of measurement
Time observation

2

Description
Pregabalin and Paracetamol Side Effects
Timepoint
First 24 hours after surgery
Method of measurement
Examination and observation of the patient

Intervention groups

1

Description
Intervention group: Administration One hour before surgery, a single dose of pregabalin 300 mg orally. And 30 minutes before the end of surgery Paracetamol 1 gr per 100cc of normal saline 0.9% diluted are given as an infusion. Also they will receive 1 gr Paracetamol per 100 cc N/S 0.9% diluted as an infusion per 6 to 24 hours after surgery
Category
Treatment - Drugs

2

Description
Intervention group: Administration a single dose of pregabalin 300 mg orally, One hour before surgery
Category
Treatment - Drugs

3

Description
Control group: Administration of placebo, One hour before surgery
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Ali hospital
Full name of responsible person
HosseinAli Soltani
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Bojnourd 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
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not 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