

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of Pregabalin with Pregabalin-Paracetamol on postoperative pain Lumbar discectomy surgery; A Randomized clinical trial

Protocol summary

Study aim

Comparison of the effect of pregabalin with pregabalin-paracetamol on pain after lumbar discectomy

Design

double-blind randomized clinical trial, phase 3 on 60 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 60 patients aged 20-60 years who are candidates for discectomy at Imam Ali Hospital of North Khorasan University of Medical Sciences. Patients are randomly assigned to two groups using a web-based system. Pain assessment will be assessed by visual analog scale pain measuring instruments at time intervals: recovery, 6, 12, 18 and 24 hours after surgery. To perform blinding, patients, surgeons, and individuals performing pain assessments at different intervals will be blinded to the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 20 to 60 years. Physical classification of grades one and two based on the guidelines of the American Anesthesia Association, non-drug addiction. Hypersensitivity to pregabalin and paracetamol. Exclusion criteria: If the patient has heart, vascular and liver problems. If the patient has a history of lumbar surgery.

Intervention groups

In the first group, the intervention will be that one hour before the operation, they receive a single dose of pregabalin 300 mg orally and 100 cc of normal 0.9% saline by infusion 30 minutes before the end of the surgery. In the second group, the intervention will be that one hour before the operation, they receive a single dose of pregabalin 300 mg orally and the drug paracetamol 1 g per 100 cc of normal saline 0.9% diluted by infusion 30 minutes before surgery. they receive.

Main outcome variables

Postoperative pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141001019359N17**

Registration date: **2023-04-19, 1402/01/30**

Registration timing: **registered_while_recruiting**

Last update: **2023-04-19, 1402/01/30**

Update count: **0**

Registration date

2023-04-19, 1402/01/30

Registrant information

Name

Hossein Zeraati

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-07, 1401/12/16

Expected recruitment end date

2023-06-06, 1402/03/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the effectiveness of Pregabalin with Pregabalin-Paracetamol on postoperative pain Lumbar discectomy surgery; A Randomized clinical trial

Public title
Comparison of the effectiveness of Pregabalin with Pregabalin-Paracetamol on postoperative pain

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 20 to 60 years ASA physical status I-II Do not have drug addiction Do not have allergic to Pregabalin and Paracetamol
Exclusion criteria:
 If the patient have used paracetamol or pregabalin 48 hours before the operation. If the patient be suffering from neurological and psychological, heart, lung, kidney and liver disease. If the patient has any history of epilepsy.

Age
From **20 years** old to **60 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
 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 groups by randomly assigned blocking using a web-based system. Random blocking at www.randomization.com will be done in 15 blocks of 4. So that in each block, there are 2 people in the first group (A), two people in the second group (B). After a random sequence was identified in all blocks, cards were written by writing A and B to indicate which group each patient was assigned to, and by someone other than the research team from 1 to 60 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. In this study, there is a placebo (normal saline) for paracetamol, patients don't know whether it is paracetamol or a placebo. Also, the clinical caregiver and the person evaluating the outcome are also aware of the interventions, but they don't know about patient's allocation. Thus, the patient, clinical caregiver, evaluator and data analyst are blinded to the study groups.

Placebo
Used

Assignment
Parallel

Other design features
 Double-Blind randomized clinical trial, Phase 3 on 60 patients, Web-Based randomization software was used for randomization.

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

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North Khorasan

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9416678894

Approval date

2022-03-14, 1400/12/23

Ethics committee reference number

IR.NKUMS.REC.1400.205

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Pain

Timepoint

Recovery, 12, 24 and 48 hours after surgery

Method of measurement

Visual Analog Score (VAS) Form of pain

Secondary outcomes

1

Description

Pregabalin and Paracetamol Side Effects

Timepoint

Up to 48 hours after surgery

Method of measurement

Examination and observation of the patient

Intervention groups

1

Description

Intervention group1 : The intervention will be one hour before the operation, receive a single dose of 300 mg Pregabalin orally and 100 cc of 0.9% normal saline by infusion 30 minutes before surgery.

Category

Prevention

2

Description

Intervention group 2: The intervention will be that one hour before the operation, they receive a single dose of Pregabalin 300 mg orally and receive 1 gram of Paracetamol per 100 cc of normal saline 0.9% diluted by infusion 30 minutes before the end of the surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali Hospital

Full name of responsible person

Javad Shahinfar

Street address

Emam Ali Hospital, Bojnurd, Iran.

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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

Bojnourd University of Medical Sciences

Full name of responsible person

Javad Shahinfar

Position

Anesthesiologist Faculty

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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