# 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 60patients, 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**
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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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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
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## Sponsors / Funding sources

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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

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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