Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Comparison of the oral Pregabalin and Gabapentin effects as a premedication in pain control after orthopedic surgery on the upper limb.

Protocol summary

Study aim

Determining the difference between the effect of pregabalin and oral gabapentin as a prodrug in controlling pain after orthopedic surgery on the upper extremities.

Design

Clinical trial without control group, with parallel groups, double-blind, randomized, phase 2 on 120 patients, for randomization of Balance-block randomization with 4 permutations will be used.

Settings and conduct

The aim of this study was to compare postoperative pain in different parts of the upper extremities in patients receiving oral pregabalin and oral gabapentin as prodrug in Imam Khomeini Hospital in Ilam. A random preoperative case will be given to a group of patients at the right time and at the right dose, and the amount of postoperative pain will be compared at several times using the VAS questionnaire. Evaluates whether the patient will be unaware of the type of medication received.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective orthopedic surgery on one of the upper limbs with general anesthesia in the age range of 55-20 years and ASA class one and two. Exclusion criteria: Dissatisfaction of patient or guardian to participate in the study, severe hemodynamic instability, neurological disease or mental disorders, pre-seizure existence, acute and chronic kidney disease despite hypersensitivity to pregabalin and gabapentin, alcohol abuse And drugs or experience chronic pain relief.

Intervention groups

For intervention in patients undergoing orthopedic surgery on the upper extremities, one of the two drugs pregabalin or gabapentin will be randomly prescribed and the analgesic effects of these two drugs will be compared.

Main outcome variables

Variables include: age; Gender; Body mass index; Place of surgery; Severity of pain after surgery; Drug consumption; Morphine intake

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211013052759N1**
Registration date: **2021-10-20, 1400/07/28**
Registration timing: **prospective**

Last update: **2021-10-20, 1400/07/28**
Update count: **0**

Registration date

2021-10-20, 1400/07/28

Registrant information

Name

Rana Roshanfekr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 4260 8531

Email address

roshanfekrrana@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-01, 1400/08/10

Expected recruitment end date

2022-04-19, 1401/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of the oral Pregabalin and Gabapentin effects as a premedication in pain control after orthopedic surgery on the upper limb.

Public title
Comparison of the oral pregabalin and gabapentin effects as a premedication in pain control after orthopedic surgery on the upper limb.

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Having elective orthopedic surgery on one of the upper limbs with general anesthesia Age range 20_55 years ASA class one and two

Exclusion criteria:
Patient or guardian dissatisfaction with participation in the study, severe hemodynamic instability, neurological disease or mental disorders, patients with a history of seizures, acute and chronic kidney disease, patients with a history of pregabalin and gabapentin allergies, alcohol and drug abuse Or a history of chronic analgesia Severe hemodynamic instability Neurological disease or mental disorders Patients with a history of seizures Acute and chronic kidney disease Patient with a history of pregabalin and gabapentin allergies alcohol and drug abuse Or a history of chronic analgesia

Age
From **20 years** old to **55 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
At the beginning, the candidates for surgery will be determined based on the entry and exit criteria, and then Balance-block randomization with 4 permutations will be used for random allocation Blocks used include: PPGG PGPG PGGP GGPP GPGP GPPG Where the letter P (pregabalin group) and the letter G (gabapentin group) will be. RAS (Research Analysis and Statistics) software will be used to generate random blocks and a random number table will be used to select each block. Hide created sequence To hide the created sequence, boxes will be installed that will be exactly the same and random codes will be written on them, and each code will indicate a type of drug, and the drug in the box will be exactly the same. The list of codes prepared for each drug will be determined by the research team. Hide created sequence: To hide the created sequence, boxes will be installed that will be exactly the same and random codes will be written on them, and each code will indicate a type of drug, and the drug in the box will be exactly the same. The list of codes prepared for each drug will be determined by the research team and the final list will be at the discretion of the lead researcher. This method will ensure that the doctor or nurse prescribing the medicine does not know the type of medicine.

Blinding (investigator's opinion)
Double blinded

Blinding description
Volunteer patients will be aware of the type of both drugs to participate in the study before receiving the drug, but will not be aware of which of the two drugs they will receive in order to blind patients. Also, the nurses who collect the data will not be aware of which of the two drugs the patient has received.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Ilam University of Medical Sciences

Street address
No. 201, Kavand dead end, Javad mosque alley, Safa st.

City
Brujerd

Province
Lorestan

Postal code
6913884343

Approval date
2021-10-09, 1400/07/17

Ethics committee reference number
IR.MEDILAM.REC.1400.129

Health conditions studied

1

Description of health condition studied
Comparison of the effect of gabapantin and oral pregabalin as a prodrug in controlling pain after orthopedic surgery on the upper limb in Imam Khomeini Hospital in Ilam.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Pain score in vas questionnaire
Timepoint
Measurement of pain intensity after recovery and 6 and 12 hours after surgery
Method of measurement
Visual analogue scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
.Intervention group: 120 patients with random entry conditions will be divided into two groups: pregabalin and gabapentin, so that there will be 60 people in each group. For the pregabalin group (P) one 150gg capsule will be prescribed one hour before surgery and for the gabapentin group 300mg will be administered two hours before the start of surgery. Patients will be given standard monitoring (blood pressure, heart rate, pulse oximetry, cardiography) at the beginning of the operating room. Patients with intravenous route No. 18 will be given 500 ml of Ringer's serum.Midazolam 1mg / kg is injected into the patient as a prodrug and at a dose of 2 mg / kg propofol and 0.5 mg / kg atracurium will be used to induce anesthesia. Will be used and after reviewing the vital signs and the appropriate depth of anesthesia, the surgeon will be allowed to begin surgery. After surgery, patients are transferred to recovery and patients are evaluated at three times (exit from recovery by anesthesiologist and at 6 and 12 hours after surgery by a nurse who is not aware of the type of medication received) for pain severity using a questionnaire. The VAS standard will be performed. In case of pain in case of pain with VAS score higher than 3, morphine will be injected intravenously at a dose of 0.1 mg / kg. The dose will be recorded in the relevant questionnaire and will continue to monitor pulse oximetry to diagnose loss of consciousness or respiratory depression in these patients, and we will even prescribe supplemental oxygen if necessary. Patients will then be evaluated for postoperative pain and the average dose of morphine in the two groups receiving pregabalin and gabapentin. Also, this comparison in gender and age subgroups and body mass index will be important for us and will be examined.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Rana Roshanfekr
Street address
Ayatollah heydari street
City
Ilam
Province
Ilam
Postal code
6913884343
Phone
+98 84 3333 8255
Email
Roshanfekrrana@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Mohammadreza Kaffashiyan
Street address
Medilam university, bangjenab, pajoohesh boulevard
City
Ilam
Province
Ilam
Postal code
6913884343
Phone
+98 84 3223 5721
Email
Roshanfekrrana@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ilam 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
Ilam University of Medical Sciences

Full name of responsible person
Rana Roshanfekr

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Anesthesiology

Street address
No.201, kavand dead end, javad mosqe alley, Safa st.

City
لرستان

Province
Lorestan

Postal code
6913884343

Phone
+98 66 4260 8531

Email
Roshanfekrrana@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ilam University of Medical Sciences

Full name of responsible person
Rana Roshanfekr

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Anesthesiology

Street address
No.201, kavand dead end, javad mosqe alley, safa st.

City
Brujerd

Province
Lorestan

Postal code
6913884343

Phone
+98 66 4260 8531

Email
Roshanfekrrana@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Ilam University of Medical Sciences

Full name of responsible person
Rana Roshanfekr

Position
Student

Latest degree
A Level or less

Other areas of specialty/work
Anesthesiology

Street address
No.201, kavand dead end, javad mosque alley, safa st.

City
Brujerd

Province
Lorestan

Postal code
6913884343

Phone
+98 66 4260 8531

Email
Roshanfekrrana@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