Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The efficacy of Pregabalin compared to placebo in management of acute postoperative pain after anterior cruciate ligament (ACL) reconstruction surgery

Protocol summary

Study aim
Effectiveness of pregabalin compared to the placebo group in improving pain after anterior cruciate ligament reconstruction surgery in the acute phase, in patients referred to Akhtar Hospital in 1402

Design
Two arm parallel group randomized Double-Blind phase 2 trial in 132 patients who undergo ACL reconstruction surgery

Settings and conduct
This double-blind study will evaluate the analgesic effect of pregabalin. Participants will randomly assign to receive pregabalin or a different placebo, with both supervising personnel and participants unaware of the method used, and unbiased assessment of pain relief and ensure its delivery. Potential sources of outcome assessor bias will be blinded. The purpose of the careful design of this study is to provide strong evidence for the analgesic effect of pregabalin.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 18-45 year old patients who undergo arthroscopic anterior cruciate ligament reconstruction surgery. Exclusion criteria: (1) any known allergy or contraindication to pregabalin. (2) History of heart, kidney or liver disease. (3) Preoperative use of antidepressants or anticonvulsants. (4) history of drug or alcohol addiction; (5) Nonsteroidal anti-inflammatory drugs (NSAIDs) or opioids use 48 hours before surgery. (6) Meniscus repair or allograft use.

Intervention groups
Pregabalin group: single dose of pregabalin 150 mg 2 hours before surgery Placebo group: one dose of placebo before surgery

Main outcome variables
Pain measured using Numeric pain scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230809059098N1**
Registration date: **2023-11-29, 1402/09/08**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-29, 1402/09/08**
Update count: **0**

Registration date
2023-11-29, 1402/09/08

Registrant information

Name
Emad Kouhestani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2206 9182

Email address
emadkouhestani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The efficacy of Pregabalin compared to placebo in management of acute postoperative pain after anterior cruciate ligament (ACL) reconstruction surgery

Public title
Effect of Pregabalin on postoperative pain after anterior cruciate ligament (ACL) reconstruction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients aged 18 to 45 who undergo arthroscopy for anterior cruciate ligament reconstruction in Akhtar Hospital in 1402 are included in the study.

Exclusion criteria:
Any known allergies or contraindications to pregabalin History of heart, kidney or liver disease Preoperative use of antidepressants or anticonvulsants History of drug or alcohol addiction Nonsteroidal anti-inflammatory drugs (NSAIDs) or opioids use 48 hours before surgery Patients who underwent meniscus reconstruction or allografts were used

Age
From **18 years** old to **45 years** old

Gender
Male

Phase
2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **132**

Randomization (investigator's opinion)
Randomized

Randomization description
In this randomized clinical trial study, patients are placed in each of the two groups according to the simple randomization method in a 1:1 ratio. The assigned group for each person is notified to the surgeon by a sealed letter.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind study, patients are studied with random identification codes assigned to them by the researcher. Patients and the person in charge of data collection are blinded to the type of patient group. Patients will be unaware of which study group they are in. Both intervention and control groups receive similar recommendations. The person in charge of data collection will be unaware of the treatment group of each patient and will record the results only based on the identification code of the people.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Shariati street

City
Tehran

Province
Tehran

Postal code
199871793

Approval date
2023-10-18, 1402/07/26

Ethics committee reference number
IR.SBMU.RETECH.REC.1402.346

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
M25.5

ICD-10 code description
Pain in joint

Primary outcomes

1

Description
Postoperative pain

Timepoint
6, 12, 24 hours postoperatively

Method of measurement
Numeric pain scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: A single dose of pregabalin from Tehran Shimi Company, 150 mg, is taken 2 hours before surgery with a glass of water.

Category
Treatment - Drugs

2

Description
Control group: A single dose placebo (capsule containing sucrose with the same shape and color as pregabalin capsule) is taken with a glass of water 2 hours before surgery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar Hospital
Full name of responsible person
Emad Kouhestani
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Sharifi Manesh street
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199871793
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Akhtar Hospital Research Center
Full name of responsible person
Emad Kouhestani
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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
Akhtar Hospital Research Center
Proportion provided by this source
100
Public or private sector
Private
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Emad Kouhestani
Position
Resident
Latest degree
Medical doctor
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Resident

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
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

Title and more details about the data/document
Collected deidentified IPD, IPD collected for the primary outcome measure only

When the data will become available and for how long
Deidentified data will be available starting from May, 2023.

To whom data/document is available
People working in academic institutions

Under which criteria data/document could be used
No specific condition

From where data/document is obtainable
Email Emad Kouhestani to obtain data
emadkouhestani@gmail.com

What processes are involved for a request to access data/document
The process is: 1- Asking a written request contain the main reasons of data importance for the applicant 2- After receiving the request letter, data will be provided in one month.

Comments