Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of oral pregabalin effects on postoperative pain control after orthopedic surgery on farcture of lower limbs in Fatemi hospital in 2011

Protocol summary

Summary

Aim of Study: Postoperative pain is among the problems which lack of control on it has many side effects. In this study we evaluated the preoperative administration of pregabalin sufficiency and security in relieving postoperative pain after lower limb orthopedic surgery and reducing the need for opioids and their possible side effects. Critical inclusion criteria: The patients candidate for lower limb surgery in pelvic, femur and leg under general anesthesia Critical exclusion criteria: Patients with pregnancy, neurological disease, psychiatric disorders, acute or chronic renal disease, history of peptic ulcer, history of allergy to pregabalin Study population and sample size: This study is a randomized, double-blind clinical trial. It is performed on 60 patients under lower limb surgery in pelvic, femur and leg who refer to Ardabil Fatemi Hospital. Patients are randomly allocated to two groups, one group receive a 150 mg pregabalin capsule 2 hours before surgery and the other group receive placebo as a control. In both groups after surgery, the patients are evaluated and the pain score, the score of sedation, incidence of nausea and vomiting during 24 hour after surgery are recorded in the checklists.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212254093N5**
Registration date: **2013-01-06, 1391/10/17**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-01-06, 1391/10/17

Registrant information

Name
Masood Entezariasl
Name of organization / entity
Ardabil University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Ardabil University of Medical Sciences

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2011-09-21, 1390/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of oral pregabalin effects on postoperative pain control after orthopedic surgery on farcture of lower limbs in Fatemi hospital in 2011

Public title

The effects of oral pregabalin on postoperative pain of lower limb fracture

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Candidate for lower limb surgery in pelvic, femur and leg under general anesthesia;ASA class I-II Exclusion criteria: Patients with

pregnancy;neurological disease;psychiatric disorders; history of seizures; acute or chronic renal disease;history of peptic ulcer;history of allergy to pregabalin or pethidine; taking psychotropic drugs;alcohol or drugs abuse;daily intake of analgesics

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ardabil University of Medical Sciences

Street address
Ardabil University of Medical Sciences

City
Ardabil

Postal code

Approval date
2010-10-12, 1389/07/20

Ethics committee reference number
882/1

Health conditions studied

1

Description of health condition studied
lower limb fracture

ICD-10 code
T12

ICD-10 code description
Fracture of lower limb, level unspecified

Primary outcomes

1

Description
pain

Timepoint
2-6-12-24 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
sedation

Timepoint
2-6-12-24 hours after surgery

Method of measurement
ramsay sedation scoring

Intervention groups

1

Description
a 150 mg pregabalin capsules 2 hours before surgery

Category
Prevention

2

Description
a placebo capsule 2 hours before surgery

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemi Hospital

Full name of responsible person
Dr Masood Entezariasl

Street address

City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Dr Akbar Pirzadeh

Street address

School of Medicine, Ardabil University of Medical Sciences, Ardabil, Iran

City

Ardabil

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ardabil University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Dr Masood Entezariasl

Position

Associate Professor of Anesthesiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty