Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A randomized clinical trial on the effects of oral Pregabalin compared with placebo in acute postoperative pain in patients who undergo Thoracotomy

Protocol summary

Summary

The main objective of this study is evaluating the effect of preoperative administration of pregabalin in relieving postoperative pain after thoracotomy surgery. This study is a randomized, double-blind clinical trial on 60 patients undergoing thoracotomy surgery in Afzalipour hospital of Kerman. Inclusion Criteria: Patients, who are admitted for thoracic surgery, age 20 to 65 year. Exclusion criteria: pregnancy, history of allergy to pregabalin, history of treatment with pregabalin or gabapentin, history of chronic pain syndromes and painkiller consumption, addiction to alcohol or drugs, allergy to pethidine, psychiatric drug consumption, surgery lasting more than 4 hours. The subjects are divided in two groups of intervention and control (receiving pregabalin and placebo respectively) randomly using simple randomization method by random number table. The patients, medicine administrator and the one responsible for recording the score of pain are blind to the used drug. The intervention group will received 300 mg pregabalin orally as a preoperative pain killer two hours prior to surgery. In control group placebo (a capsule similar to original drug without effective substance) is given. The method of anesthesia for both is alike. At the end of operation and transferring to recovery room, the score of pain is measured every 15 minutes for an hour and after transporting to ward, every 4 hours for 24 hours by means of VISUAL ANALOGUE SCALE.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014110210900N4**
Registration date: **2016-04-05, 1395/01/17**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2016-04-05, 1395/01/17

Registrant information

Name

Hosein Sattari

Name of organization / entity

kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 1322 2250

Email address

sattari@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Kerman University of Medical Sciences

Expected recruitment start date

2014-01-19, 1392/10/29

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A randomized clinical trial on the effects of oral Pregabalin compared with placebo in acute postoperative pain in patients who undergo Thoracotomy

Public title

analgesic effects of a drug in thoracic surgeries

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Patients, who are admitted for thoracic surgery, age 20 to 65 year. Exclusion criteria: pregnancy, history of allergy to pregabalin, history of treatment with pregabalin or gabapentin, history of chronic pain syndromes and painkiller consumption, addiction to alcohol or drugs, allergy to pethidine, psychiatric drug consumption, surgery lasting more than 4 hours, uncontrolled blood pressure, history of convulsion and the patients who had preoperative pain based on the visual analogue scale (VAS) had preoperative pain.
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
2
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
The ethics committee of Kerman University of Medical sciences
Street address
Shafa Square
City
Kerman
Postal code
Approval date
2014-02-19, 1392/11/30
Ethics committee reference number
k/92/489

Health conditions studied

1

Description of health condition studied
Acute pain
ICD-10 code
R52.0
ICD-10 code description
Acute pain

Primary outcomes

1

Description
pain
Timepoint
At the end of operation and transferring to recovery room, the score of pain is measured every 15 minutes for an hour and after transporting to ward, every 4 hours for 24 hours
Method of measurement
VISUAL ANALOGUE SCALE

Secondary outcomes

1

Description
the dose of analgesic
Timepoint
during and after surgery
Method of measurement
recording the dose and frequency of administration

Intervention groups

1

Description
In intervention group, 300 mg pregabalin is administered orally as an analgesic, 2 hours before surgery
Category
Treatment - Drugs

2

Description
In control group placebo (a capsule similar to the drug without any effective substance) is administered.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipoor Hospital
Full name of responsible person
Hosseyn Sattari
Street address

Afzalipoor Hospital, Zendan Square

City

Kerman

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Hassani

Street address

Tahmasbabad Square, Ebnesina Street

City

Kerman

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Hosein Sattari

Position

assistant professor of anesthesiology

Other areas of specialty/work

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Contact

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medical student

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Person responsible for updating data

Contact

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Position

Assistant 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