Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of of single dose amitriptiline versus pregabalin on postoperative pain reduction in patients after spinal surgery

Protocol summary

Summary

The purpose of this study is the comparative study of single dose amitriptyline versus pregabalin on postoperative pain reduction after spinal surgery patients. In this randomized, double blind clinical trial, a number of seventy-two patients, twenty to sixty years old, Inclusion criteria: candidate for elective spinal surgery; lack of severe systemic and mental disease; consent to participate in the study and exclusion criteria: history of drug allergy; opiate use; sedative use enrolled in the study. They are randomly divided into three groups: placebo and amitriptyline and Pregabalin. . Thirty min before induction of anesthesia the control group received placebo orally second group takes 25 milligrams amitriptyline and third group 300 milligrams Pregabalin. at the end of surgery after transferring to the ward, one, four and six hours after surgery pain measure and record by collaborator who does not know about grouping by using the Visual Analogue Scale and statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201406151617N9**
Registration date: **2015-10-04, 1394/07/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-04, 1394/07/12

Registrant information

Name

Mansour Choubsaz

Name of organization / entity

Imam Reza Hospital

Country

Iran (Islamic Republic of)

Phone

+98 83 1724 6708

Email address

mchoubsaz@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2014-03-20, 1392/12/29

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of of single dose amitriptiline versus pregabalin on postoperative pain reduction in patients after spinal surgery

Public title

comparision of single dose amitriptiline versus pregabalin on postoperative pain reduction after spinal surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: candidate for elective spinal surgery; lack of severe systemic and mental disease; consent to participate in the study Exclusion criteria: history of drug allergy; opiate use; sedative use

Age

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

Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **72**
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
Ethic Committee of Kermanshah University of Medical Sciences
Street address
Kermanshah University of Medical Sciences
City
Kermanshah
Postal code
6718938179
Approval date
2014-09-06, 1393/06/15
Ethics committee reference number
23312

Health conditions studied

1

Description of health condition studied
Low back pain
ICD-10 code
M54.1
ICD-10 code description
Radiculopathy

Primary outcomes

1

Description
pain
Timepoint
0,1,4,6 hours after surgery
Method of measurement
Visual analogue score

Secondary outcomes

empty

Intervention groups

1

Description
amitriptyline 25 mg oral tablet with a glass of water 30 minutes before induction of anesthesia
Category
Prevention

2

Description
Pregabalin 300 mg oral tablet with a glass of water 30 minutes before induction of anesthesia
Category
Prevention

3

Description
Placebo oral tablet with a glass of water 30 minutes before induction of anesthesia
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Kermanshah University of Medical Sciences
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr.Hosein Karim
Street address
Kermanshah University of Medical Sciences
City
Kermanshah
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Tayebeh Khademi
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Person responsible for updating data

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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