Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The Effects of Pregabalin on Agitation and Pain after Coronary Artery Bypass Graft Surgery

Protocol summary

Summary

Objectives: The aim of this study was to investigate the effects of pregabalin on the agitation and pain after coronary artery bypass graft surgery. Design of the study: randomized double blind clinical trial. Inclusion criteria: Patients who undergo coronary artery bypass graft surgery. exclusion criteria: EF < 35%, Cr > 1.5, BMI > 35, chronic alcohol consumers, drug addicts, epileptic patients, patients with insulin dependent diabetes mellitus ', recent use of gabapentin, uncontrolled blood pressure, liver failure, the sensitivity of the Pregabalin, return to the operating room during the study period, the patient's re-intubation during the first 3 days after the surgery, mortality during the first 3 days. Sample Size: 94 patients found eligible based on the inclusion criteria. Patients were randomly divided into two groups of intervention group and placebo group. Patients in the intervention group received 150 mg pregabalin, 2 hours before surgery and 75 mg pregabalin at the first, second and third days after surgery in the hours of 9 am and 9 pm and patients in the placebo group received one capsule placebo at the same time. The written forms of VAS and RASS were completed at 11 am and 11 pm. On the other hand, the amount of other analgesic drugs was considered in the study in addition to the pregabalin for controlling pain and agitation in the intensive care unit.

General information

Acronym

RASS (Richmond agitation sedation scale),VAS(Visual analogue scale)

IRCT registration information

IRCT registration number: **IRCT2014101719470N2**
Registration date: **2015-01-16, 1393/10/26**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-01-16, 1393/10/26

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Shiraz University of Medical Science

Expected recruitment start date

2015-02-01, 1393/11/12

Expected recruitment end date

2015-03-06, 1393/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Pregabalin on Agitation and Pain after Coronary Artery Bypass Graft Surgery

Public title

The Effects of Pregabalin on Agitation and Pain after Cardiac Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who undergo coronary artery bypass graft surgery. exclusion criteria: EF < 35%, Cr > 1.5, BMI > 35, chronic alcohol consumers, drug addicts, epileptic patients, patients with insulin dependent diabetes mellitus ', recent use of gabapentin, uncontrolled blood pressure, liver failure, the sensitivity of the Pregabalin, return to the operating room during the study period, the patient's re-intubation during the first 3 days after the surgery, mortality during the first 3 days.

Age
No age limit

Gender
Male

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **94**

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 Shiraz University Of Medical Sciences

Street address
Central Building of Shiraz University of Medical Sciences, Zand Street

City
Shiraz

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
CP-P-9364-6444

Health conditions studied

1

Description of health condition studied
Coronary Artery Bypass Graft

ICD-10 code
125.1

ICD-10 code description
Atherosclerotic Heart Disease

Primary outcomes

1

Description
Pain

Timepoint
Twice at Three Days after Surgery

Method of measurement
,VAS(Visual Analogue Scale

Secondary outcomes

1

Description
Agitation

Timepoint
Twice at Three Days after Surgery

Method of measurement
Richmond agitation sedation scale

Intervention groups

1

Description
Patients in the intervention group received 150 mg pregabalin, 2 hours before surgery and 75 mg pregabalin at the first, second and third days after surgery in the hours of 9 am and 9 pm .

Category
Treatment - Drugs

2

Description
Patients in the control group received one capsule placebo , 2 hours before surgery and at the first, second and third days after surgery in the hours of 9 am and 9 pm

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Namazi Hospital

Full name of responsible person
Sudabeh Emami

Street address
Anesthesiology Office, Namazi Hospital, Zand Street

City

Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Seed BasirHashemi
Street address
Central Building of Shiraz University of Medical Sciences, Zand Street
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Sudabeh Emami
Position
Physician, Anesthesiology Resident
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University Of Medical Sciences
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Reza Jouybar
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Anesthesiologist
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Person responsible for updating data

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Shiraz University of Medical Sciences
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00
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Web page address

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