

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Gabapentin on prevention of delirium in patients undergoing coronary artery bypass graft surgery

Protocol summary

Study aim

Effect of gabapentin on prevention of delirium in patients undergoing coronary artery bypass graft surgery

Design

a randomized triple blind placebo control clinical trial

Settings and conduct

58 patients undergoing coronary artery bypass graft surgery at Yazd Afshar Hospital were randomly assigned to one drug before surgery and the first and second days after surgery. Patient, researcher, physician, nurse, analyzer did not know the contents of the capsule medication.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients who were candidates for coronary artery bypass surgery were included in the study. Exclusion criteria: 1)History of taking anticonvulsants 2)History of Gabapentin use in the last two weeks 3)Proven history of psychiatric problem (psychosis) 4)Emergency Surgery 5)ICU admission before surgery 6)Delirium before surgery 7)Previous cardiac surgery history

Intervention groups

Patients undergoing coronary artery bypass graft surgery receive one capsule of code A or B one hour prior to surgery based on the randomized number table. They receive one capsule on the first and second day after surgery. Trained nurses will be evaluated according to the CAM-ICU criteria at 6 pm and 12 pm and recorded in the appropriate form. If the patient showed signs of delirium out of the above hours, the extra form for the patient became full and replaced one of the normal forms of the day.

Main outcome variables

Prevention of delirium after surgery and reduction of hospital stay and mortality and morbidity after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200306046706N1**

Registration date: **2020-04-16, 1399/01/28**

Registration timing: **retrospective**

Last update: **2020-04-16, 1399/01/28**

Update count: **0**

Registration date

2020-04-16, 1399/01/28

Registrant information

Name

Elham Farzannejad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3623 7273

Email address

elhamfarzannejad@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

2019-02-20, 1397/12/01

Actual recruitment end date

2020-01-21, 1398/11/01

Trial completion date

2020-01-21, 1398/11/01

Scientific title

The effect of Gabapentin on prevention of delirium in patients undergoing coronary artery bypass graft surgery

Public title

Effect of Gabapentin on prevention of Delirium

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients undergoing Coronary Artery Bypass Graft Surgery

Exclusion criteria:

History of taking anticonvulsants, History of Gabapentin drugs consumption in the last two weeks History of proven psychological problems Emergency surgery ICU Admission before surgeon Delirium before surgery History of previous cardiac surgery

Age

From **45 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Using a Random Number Table, Individuals in two groups A and B were included in the study

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant: After giving informed consent, they entered the intervention groups. Investigator: Not knowing which group A and B are medication and placebo. Physician and nurse: Not knowing which group A and B are medication and placebo. Outcome assessor: Not knowing which group A and B are medication and placebo. Data analyzer: Not knowing which group A and B are medication and placebo.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Yazd University of Medical Sciences

Street address

Second Kui, Shahid Ashtarzadeh Alley, Maskan Street, Kashani Ave

City

Yazd

Province

Yazd

Postal code

8915664167

Approval date

2019-02-05, 1397/11/16

Ethics committee reference number

IR.SSU.MEDICINE.REC.1398.105

Health conditions studied**1****Description of health condition studied**

Coronary Heart Disease, Delirium, Open Coronary Heart Surgery

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes**1****Description**

Permitted delirium according to the CAM-IC criteria

Timepoint

Examine delirium twice daily, days 1, 2, 3

Method of measurement

Confusion Assessment Method-ICU

Secondary outcomes**1****Description**

Postoperative mortality

Timepoint

Death occurring from 36 hours to one month after surgery

Method of measurement

Phone Follow up

Intervention groups**1****Description**

Intervention group: Gabapentin 400 mg capsule, daily, for three days, with sufficient water in the morning, prepared by the Pharmacology Group.

Category

Prevention

2

Description

Control group: Multivitamin Capsule, daily, for three days, in the morning with sufficient amount of water, prepared by Pharmacology Group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Hospital

Full name of responsible person

Elham Farzannejad

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Second Kui, Shahid Ashtarzadeh Alley, Maskan Street, Kashani Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Massoud Mirzaei

Street address

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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

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

IR

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Elham Farzannejad

Position

Assistant

Latest degree

Subspecialist

Other areas of specialty/work

Psychiatrics

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Person responsible for scientific inquiries

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Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Elham Farzannejad

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Person responsible for updating data

Contact

Name of organization / entity
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Postal code

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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