

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of gabapentin versus placebo on delirium after surgery in patients with coronary artery bypass graft: a double-blind randomized clinical trial

Protocol summary

Study aim

To assess the effect of gabapentin versus placebo on delirium after surgery in patients with coronary artery bypass graft

Design

This is a double-blind randomized clinical trial, in which 68 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients who are candidate for coronary artery bypass graft surgery referring to the Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots. This trial will be double-blinded so that neither patients nor the physician examining the patients will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 75 years, Candidate for coronary artery bypass graft, Exclusion criteria: Sensitivity to gabapentin medication

Intervention groups

Intervention group: Two gabapentin capsules 400 mg (manufactured by Oxir Pharmaceutical Co.) 2 hours before surgery and then on gabapentin capsule 400 mg every 12 hours for 3 das Control group: Two placebo capsules (containing starch) 2 hours before surgery and then on placebo capsule 400 mg every 12 hours for 3 das

Main outcome variables

Primary outcome: delirium Secondary outcome: Probable side effect including drowsiness, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N393**

Registration date: **2021-05-03, 1400/02/13**

Registration timing: **prospective**

Last update: **2021-05-03, 1400/02/13**

Update count: **0**

Registration date

2021-05-03, 1400/02/13

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-07-06, 1400/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of gabapentin versus placebo on delirium after surgery in patients with coronary artery bypass graft: a double-blind randomized clinical trial

Public title

Effect of gabapentin versus placebo on delirium after surgery in patients with coronary artery bypass graft

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age of 18 to 75 years, Candidate for coronary artery bypass graft,

Exclusion criteria:

Sensitivity to gabapentin medication

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The shape of the medications and placebos will be perfectly the same. Therefore, patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Thus, the trial will be run as double-blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,

Hamadan University of Medical Sciences, Shahid

Fahmideh Ave

City

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Postal code

6517838695

Approval date

2019-11-23, 1398/09/02

Ethics committee reference number

IR.UMSHA.REC.1398. 687

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

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

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

Measuring delirium

Timepoint

Before surgery and 3 days after that

Method of measurement

Using Visual Analog Scale (VAS)

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

Probable side effect including drowsiness, nausea and vomiting

Timepoint

up to 3 days after surgery

Method of measurement

By history taking

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

Intervention group: Two gabapentin capsules 400 mg (manufactured by Oxir Pharmaceutical Co.) 2 hours before surgery and then on gabapentin capsule 400 mg every 12 hours for 3 das

Category

Treatment - Drugs

2

Description

Control group: Two placebo capsules (containing starch)
2 hours before surgery and then on placebo capsule 400
mg every 12 hours for 3 das

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital in Hamadan city

Full name of responsible person

Dr Parya Sayarfar

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Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr Parya Sayarfar

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

Professor of Epidemiology

Latest degree

Ph.D.

Other areas of specialty/work

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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