

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### Study of Gabapentin effects on morphine consumption and pain after adult heart surgery

#### Protocol summary

##### Summary

Background and aims : The purpose of this study is evaluating of analgesic effect of preemptive gabapentin on postoperative pain and morphine consumption after cardiac surgery. Methods: A double-blind randomized clinical trial in 60 males candidate for coronary bypass surgery. Patients were grouped as gabapentin (n=30) and control group (n=30). Gabapentin group received 800 mg orally two hours before surgery and 400 mg two hours post extubation. Control group received placebo with same period. Outcome: amount of pain according to 11-point numerical scale and cumulative morphine consumption and the incidence of side effects and hemodynamic changes at 2, 6, 12, 18, 24 hours Post extubation.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201103065990N1**

Registration date: **2011-05-14, 1390/02/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2011-05-14, 1390/02/24

##### Registrant information

###### Name

Aminolah Vasigh

###### Name of organization / entity

Ahwaz Jundishapour university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

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##### Recruitment status

**Recruitment complete**

##### Funding source

Ahwaz Jundishapour University of Medical Sciences

##### Expected recruitment start date

2009-06-11, 1388/03/21

##### Expected recruitment end date

2011-03-20, 1389/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of Gabapentin effects on morphine consumption and pain after adult heart surgery

##### Public title

Evaluating analgesic effect of Gabapentin on postoperative pain and morphine consumption after cardiac surgery

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: men aged 20-70 years undergoing coronary artery bypass graft surgery. Exclusion criteria: history of chronic analgesic use (nonsteroidal anti-inflammatory drugs, opioids, or paracetamol); tranquilizer, anticonvulsant, or antidepressant use; alcohol dependence; malabsorption; hepatic and renal insufficiency; emergency surgery; previous cardiac surgery; left ventricular dysfunction (ejection fraction <40%); preoperative use of inotropic agents or intraaortic balloon pump; and allergy to the study drugs. Patients undergoing redo sternotomy were also excluded from the study.

**Age**

From **20 years** old to **70 years** old

**Gender**

Male

**Phase**

2-3

**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**

Ahvaz Jondishapour university of medical sciences

**Street address**

Shahr-e Daneshgah

**City**

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**Postal code**

6135715794

**Approval date**

2010-06-10, 1389/03/20

**Ethics committee reference number**

2629/20/8/پ

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

pain relief after CABG surgery

**ICD-10 code**

R52.0

**ICD-10 code description**

Acute pain

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

morphine consumption

**Timepoint**

2, 6, 12, 24 hours post extubation

**Method of measurement**

medical records

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

pain

**Timepoint**

2, 6, 12, 18 hours after extubation

**Method of measurement**

clinical evaluation (NRS)

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

Intervention group received 800 mg orally two hours before surgery and 400 mg two hours post extubation.

**Category**

Prevention

**2****Description**

control group received placebo with same period.

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emam hospital

**Full name of responsible person**

Dr. Mansour Soltanzadeh

**Street address**

Azadegan St.

**City**

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz Jondishapur University of Medical Sciences

**Full name of responsible person**

Dr. Mostafa Feghhi

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**City**

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**Grant name**

129006  
**Grant code / Reference number**  
10506  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Ahvaz Jundishapur 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

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## Person responsible for scientific inquiries

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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