Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of the effectiveness of Gabapentin on the hs-CRP level in patients with non ST-elevation myocardial infarction

Protocol summary

Study aim
Evaluation of the effectiveness of Gabapentin on the hs-CRP level in patients with non ST-elevation myocardial infarction

Design
Phase 2 randomized double-blinded placebo parallel clinical trial on 80 patients Randomization using Randomaization.com

Settings and conduct
This study will perform in the heart ward and clinic of Imam Reza Hospital in Mashhad. Patients are randomly assigned to gabapentin and placebo groups. Patients and the main researcher are unaware of groups assignation.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with non-ST-elevation MI based on the American Heart Association criteria; Consent to admission to the study; Age over 18 years; No alternating use of alprazolam and opioids during the admission; No kidney failure under hemodialysis; No kidney failure and GFR<30; No thrombocytopenia; No severe liver failure with liver enzymes more than 3 times normal; No treatment with corticosteroids or immunosuppressive drugs; No treatment with diltiazem or verapamil; No history or prone to suicide; No history of gabapentin use; Not engaging in sensitive jobs such as driving, piloting, police. Exclusion criteria: Lack of consent to continue the study

Intervention groups
Intervention group: Patients with non-ST-elevation MI receiving gabapentin 300 mg once daily at 8 pm for one month along with common treatments Placebo group: Patients with non-ST-elevation MI receiving a placebo capsule once daily at 8 pm for one month along with common treatments

Main outcome variables
Primary outcome: Changes in the hs-CRP levels at the beginning of the study and after 4 weeks of treatment. Secondary outcome: Changes in the level of CBC diff. and lipid profile at the beginning of the study and after 4 weeks of treatment.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220516054874N2**
Registration date: **2022-07-11, 1401/04/20**
Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**
Update count: **0**

Registration date
2022-07-11, 1401/04/20

Registrant information

Name
Vafa Baradaran Rahimi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 3800 2301

Email address
baradaranrv@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2024-07-22, 1403/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of the effectiveness of Gabapentin on the hs-CRP level in patients with non ST-elevation myocardial infarction

Public title
Evaluation of the effect of Gabapentin in patients with myocardial infarction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with non-ST-elevation MI according to the American College of Heart criteria Consent to admission to the study Age more than 18 years old No use of alprazolam and opioids in the admission No kidney failure under hemodialysis No kidney failure and GFR<30 No thrombocytopenia No severe liver failure with liver enzymes three times more than normal No treatment with corticosteroids or immunosuppressive drugs No treatment with diltiazem or verapamil No history or prone to suicide No previous treatment with gabapentin Not engaging in sensitive jobs such as driving, piloting, police

Exclusion criteria:
Lack of consent to continue the study

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
The blocked randomization method is used. The volume of each block will be four. Then the list of blocks is written and numbers assigned to them, for example (AABB(1)- BBAA(2)- BABA(3)- BAAB(4)), which will be 17 blocks according to the sample size of 68. Then random numbers between 1 and 17 are selected according to the randomization site Randomaization.com and finally, the treatment allocation list is determined based on the random numbers.

Blinding (investigator's opinion)
Double blinded

Blinding description
Using sealed envelopes Due to the use of a placebo similar to the intervention treatment, the investigator and the participants will not be informed of the assigned treatment, and the analyst will also be unaware of the assigned treatment for the two groups. Finally, after analyzing the data, the researcher who prepared the packages will reveal the codes A and B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic's committee of Mashhad University of Medical Sciences

Street address
Qurashi Building, Next to Hoveyzeh Cinema, University Street, Mashhad

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2022-05-10, 1401/02/20

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.122

Health conditions studied

1

Description of health condition studied
Myocardial infarction with non-ST elevation

ICD-10 code
I21.4

ICD-10 code description
Non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Changes in hs-CRP serum level

Timepoint
At the beginning of the study and after 4 weeks of treatment

Method of measurement
Laboratory kit

Secondary outcomes

1

Description

Changes in CBC diff

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

2

Description

Changes in lipid profile

Timepoint

At the beginning of the study and after 4 weeks of treatment

Method of measurement

Laboratory kit

Intervention groups

1

Description

Intervention group: NSTEMI patients receiving gabapentin 300 mg once daily at 8 pm for one month along with standard treatment

Category

Treatment - Drugs

2

Description

Control group: NSTEMI patients receiving placebo capsule once daily at 8 pm for one month along with standard treatment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Cardiology, Imam Reza Hospital

Full name of responsible person

Dr. Arash Gholoobi

Street address

Imam Reza hospital, Ebnsina Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Majid Ghayour-Mobarhan

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Vafa Baradaran Rahimi

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Vafa Baradaran Rahimi

Position
Assistant professor

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Person responsible for updating data

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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