

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effects of Ellagic acid on the hs-CRP level in patients with myocardial infarction

Protocol summary

Registration timing: **prospective**

Study aim

Evaluation of the effectiveness of Ellagic acid on the hs-CRP level in patients with myocardial infarction

Last update: **2023-06-08, 1402/03/18**

Update count: **0**

Design

Phase 2 randomized double-blinded placebo parallel clinical trial on 60 patients Randomization using Randaomaization.com

Registration date

2023-06-08, 1402/03/18

Settings and conduct

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

Registrant information

Name

Vafa Baradaran Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3800 2301

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baradaranrv@mums.ac.ir

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with myocardial infarction based on the American Heart Association criteria; Consent to admission to the study; Age over 18 years; No kidney failure under hemodialysis; No kidney failure and GFR<30; No severe liver failure with liver enzymes more than 3 times normal; No treatment with diltiazem or verapamil Exclusion criteria: Lack of consent to continue the study

Recruitment status

Recruitment complete

Funding source

Intervention groups

Patients with myocardial infarction receiving Ellagic acid 200 mg once daily for one month along with common treatments

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2025-06-22, 1404/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

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., lipid profile, and interleukin-6 at the beginning of the study and after 4 weeks of treatment.

Scientific title

Evaluation of the effects of Ellagic acid on the hs-CRP level in patients with myocardial infarction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054874N8**

Registration date: **2023-06-08, 1402/03/18**

Public title

Evaluation of the effects of Ellagic acid on patients with myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with myocardial infarction according to the American College of Heart criteria
Consent to admission to the study
Age more than 18 years old
No kidney failure under hemodialysis
No kidney failure and GFR<30
No severe liver failure with liver enzymes three times more than normal
No treatment with diltiazem or verapamil
No previous treatment with Ellagic acid

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: **60**

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 15 blocks according to the sample size of 60. Then random numbers between 1 and 15 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)
Triple 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

13944-91388

Approval date

2023-02-27, 1401/12/08

Ethics committee reference number

IR.MUMS.IRH.REC.1401.086

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and 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

3

Description
Changes in Interleukin-6 level
Timepoint
At the beginning of the study and after 4 weeks of treatment
Method of measurement
Laboratory kit

Intervention groups

1

Description
Intervention group: Patients with myocardial infarction receiving Ellagic acid 200 mg once daily for one month along with standard treatment
Category
Treatment - Drugs

2

Description
Control group: Patients with myocardial infarction receiving placebo capsule with the same shape and size once daily 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. Vafa Baradaran Rahimi
Street address
Imam Reza hospital, Ebnsina Blvd
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+98 51 3854 3031
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baradaranrv@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Mashhad University of Medical Sciences
Full name of responsible person
Dr. Majid Ghayour-Mobarhan
Street address
Qurashi Building, Next to Hoveyzeh Cinema,
University Street, Mashhad
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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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Ghaeem hospital, Ahmadabad Blvd, Mashhad
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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

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

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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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