

# 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

##### Study aim

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

##### Design

Phase 2 randomized double-blinded placebo parallel clinical trial on 60 patients Randomization using Randaizaation.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 Ellagic acid and placebo groups. Patients and the main researcher are unaware of groups assignation.

##### 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

##### Intervention groups

Patients with myocardial infarction receiving Ellagic acid 200 mg once daily 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., lipid profile, and interleukin-6 at the beginning of the study and after 4 weeks of treatment.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220516054874N8**

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

Registration timing: **prospective**

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

Update count: **0**

##### Registration date

2023-06-08, 1402/03/18

##### 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

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

##### Scientific title

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

##### 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  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913316  
**Phone**  
+98 51 3854 3031  
**Email**  
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  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9138813944  
**Phone**  
+98 51 3841 1538  
**Email**  
Ramresearch@mums.ac.ir

**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  
**Street address**  
Ghaeem hospital, Ahmadabad Blvd, Mashhad  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9177948564  
**Phone**  
0095 5138012739  
**Email**  
baradaranrv@mums.ac.ir

## 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

**Street address**

Ghaeem hospital, Ahmadabad Blvd, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

0095 5138012739

**Email**

baradaranrv@mums.ac.ir

## 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

**Street address**

Ghaeem hospital, Ahmadabad Blvd, Mashhad

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9177948564

**Phone**

0095 5138012739

**Email**

baradaranrv@mums.ac.ir

## 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