

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

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

Protocol summary

Study aim

Evaluation of the effectiveness of Montelukast 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 Randaomaization.com

Settings and conduct

This study will perform in the heart ward and clinic of Ghaem Hospital in Mashhad. Patients are randomly assigned to Montelukast 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 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 Montelukast use. Exclusion criteria: Lack of consent to continue the study

Intervention groups

Intervention group: Patients with non-ST-elevation MI receiving Montelukast 10 mg twice daily for one month along with common treatments. Placebo group: Patients with non-ST-elevation MI receiving a placebo tablets twice 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: **IRCT20220516054874N4**

Registration date: **2022-07-19, 1401/04/28**

Registration timing: **prospective**

Last update: **2022-07-19, 1401/04/28**

Update count: **0**

Registration date

2022-07-19, 1401/04/28

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

2022-08-06, 1401/05/15

Expected recruitment end date

2024-08-05, 1403/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Evaluation of the effect of Montelukast 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 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 Montelukast

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

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 Randomization.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

Ethics 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

2022-05-24, 1401/03/03

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.187

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

3

Description

Changes in Interleukin-6 levels

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 montelukast 10 mg twice daily for one month along with standard treatment

Category

Treatment - Drugs

2

Description

Control group: NSTEMI patients receiving placebo tablet twice daily for one month along with standard treatment

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital in Mashhad

Full name of responsible person

Dr. Bahram Shahri

Street address

Ghaem hospital, Ahmadabad Blvd, Mashhad

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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

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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Person responsible for scientific inquiries

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Full name of responsible person

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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