Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

Evaluation of the effectiveness of Portulaca oleracea L. seed extract on the hs CRP level in patients with myocardial infarction

Protocol summary

Study aim

Evaluation of the effectiveness of Portulaca oleracea L. seed extract on the hs-CRP level in patients with 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 Portulaca oleracea L. seed extract and placebo groups. Patients and the main researcher are unaware of groups assignation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with 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 Exclusion criteria: Lack of consent to continue the study

Intervention groups

Intervention group: Patients with MI receiving Portulaca oleracea L. seed extract 600 mg twice daily after meal for one month along with common treatments Placebo group: Patients with MI receiving a placebo capsule 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 IL-6 at the beginning of the study and after 4 weeks of treatment.

General information

Reason for update

Due to the sampling conditions and the prolongation of the student's thesis, the sampling range was changed from patients with non-ST segment elevation myocardial infarction to patients with myocardial infarction.

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054874N3**
Registration date: **2022-07-17, 1401/04/26**
Registration timing: **prospective**

Last update: **2023-04-03, 1402/01/14**
Update count: **1**

Registration date

2022-07-17, 1401/04/26

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

2023-04-04, 1402/01/15

Expected recruitment end date

2025-02-19, 1403/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Portulaca oleracea L. seed extract on the hs CRP level in patients with myocardial infarction

Public title
Evaluation of the effect of Portulaca oleracea L. seed extract in patients with myocardial infarction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with 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

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
2022-05-17, 1401/02/27

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.131

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: MI patients receiving Portulaca oleracea L. seed extract 300 mg twice daily for one month along with standard treatment

Category

Treatment - Drugs

2

Description

Control group: MI patients receiving placebo capsule twice 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. 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

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Mashhad University of Medical Sciences
Full name of responsible person
Dr. Vafa Baradaran Rahimi
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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