

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Sep 2026

Evaluation of the effects of hawthorn extract (*Crataegus monogyna*) on the hs-CRP level in patients with myocardial infarction

Protocol summary

Study aim

Evaluation of the effects of hawthorn extract (*Crataegus monogyna*) on the hs-CRP level in patients with myocardial infarction

Design

Phase 2-3 randomized triple-blinded placebo parallel clinical trial on 60 patients; Randomization using Randomization.com

Settings and conduct

This study will perform in the heart ward of Ghaem Hospital in Mashhad. Patients are randomly assigned to Trigonella foenum graecum seed extract 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. Not-inclusion criteria: Kidney failure under hemodialysis; Severe liver failure with liver enzymes more than 3 times normal; History of using medicinal products containing *Crataegus monogyna* extract.

Intervention groups

Patients with myocardial infarction receiving *Crataegus monogyna* extract twice a day for 40 days along with common treatments

Main outcome variables

Changes in the hs-CRP levels

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054874N11**

Registration date: **2023-09-19, 1402/06/28**

Registration timing: **prospective**

Last update: **2023-09-19, 1402/06/28**

Update count: **0**

Registration date

2023-09-19, 1402/06/28

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

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-23, 1402/07/01

Expected recruitment end date

2025-09-23, 1404/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of hawthorn extract (*Crataegus monogyna*) on the hs-CRP level in patients with myocardial infarction

Public title

Evaluation of the effects of hawthorn extract (*Crataegus monogyna*) 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 Exclusion criteria: Kidney failure under hemodialysis Severe liver failure with liver enzymes three times more than normal History of using medicinal products containing Crataegus monogyna extract Age From 18 years old Gender Both Phase 2-3 Groups that have been masked • Participant • Investigator • Outcome assessor • Data analyser	Name of ethics committee Research Ethics Committee of Imam Reza Hospital Educational, Research and Treatment Center, Mashhad Street address Imam Reza Hospital educational complex building, Imam Reza Hospital, Mashhad City Mashhad Province Razavi Khorasan Postal code 9137913316 Approval date 2023-04-10, 1402/01/21 Ethics committee reference number IR.MUMS.IRH.REC.1402.019
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 Blinding will performed 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	Health conditions studied <u>1</u> 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
Secondary Ids empty Ethics committees <u>1</u> Ethics committee	Primary outcomes <u>1</u> Description Changes in hs-CRP serum level Timepoint At the beginning of the study and after 40 days of treatment Method of measurement Laboratory kit Secondary outcomes <u>1</u> Description Changes in CBC diff Timepoint At the beginning of the study and after 40 days of treatment Method of measurement Laboratory kit <u>2</u> Description Changes in lipid profile Timepoint At the beginning of the study and after 40 days of treatment Method of measurement

Laboratory kit

Intervention groups

1

Description

Intervention group: Patients with myocardial infarction receiving Crataegus monogyna extract (400 mg, prepared by Dineh company) twice a day for one 40 days along with standard treatment.

Category

Treatment - Drugs

2

Description

Control group: Patients with myocardial infarction receiving placebo tablet with the same shape and size twice a day for 40 days 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. Vafa Baradaran Rahimi

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. Mohsen Tafaghodi

Street address

Qurashi Building, Next to Hoveyzeh Cinema,
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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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Person responsible for updating data**Contact****Name of organization / entity**

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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