

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Sep 2026

Evaluation of the effects of hawthorn extract (*Crataegus monogyna*) on left ventricular ejection fraction in patients with Anterior ST segment elevation acute myocardial infarction (Anterior STEMI) treated with primary PCI

Protocol summary

Study aim

Evaluation of the effects of hawthorn extract (*Crataegus monogyna*) on left ventricular ejection fraction in patients with Anterior ST-segment elevation acute myocardial infarction treated with primary PCI

Design

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

Settings and conduct

This study will be performed 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 the group assignation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Anterior ST-segment elevation acute myocardial infarction according to the American College of Heart 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; History of heart disease and important valvular diseases in recent echocardiography.

Intervention groups

Patients with Anterior ST-segment elevation acute myocardial infarction treated with primary PCI receiving *Crataegus monogyna* extract twice a day for 40 days along with common treatments

Main outcome variables

Left ventricle ejection fraction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220516054874N12**

Registration date: **2023-09-23, 1402/07/01**

Registration timing: **prospective**

Last update: **2023-09-23, 1402/07/01**

Update count: **0**

Registration date

2023-09-23, 1402/07/01

Registrant information

Name

Vafa Baradaran Rahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2301

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baradaranrv@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2025-10-07, 1404/07/15

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 left ventricular ejection fraction in patients with Anterior ST segment elevation acute myocardial infarction (Anterior STEMI) treated with primary PCI		Placebo Used Assignment Parallel Other design features
Public title Evaluation of the effects of hawthorn extract on left ventricular ejection fraction in patients with Anterior ST segment elevation acute myocardial infarction treated with primary PCI		
Purpose Treatment		
Inclusion/Exclusion criteria Inclusion criteria: Patients with Anterior ST-segment elevation acute 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 History of heart disease and important valvular diseases in recent echocardiography		
Age From 18 years old		
Gender Both		
Phase 2-3		
Groups that have been masked • Participant • Investigator • Outcome assessor • 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 Randaomization.com and finally, the treatment allocation list is determined based on the random numbers.		
Blinding (investigator's opinion) Double 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.		
Secondary Ids empty		
Ethics committees 1 Ethics committee 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 2023-05-01, 1402/02/11 Ethics committee reference number IR.MUMS.IRH.REC.1402.057		
Health conditions studied 1 Description of health condition studied Acute anterior ST elevation Myocardial infarction treated with primary PCI ICD-10 code I21 ICD-10 code description ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction		
Primary outcomes 1 Description Left ventricle ejection fraction Timepoint At the beginning of the study and after 40 days of treatment Method of measurement Echocardiography		
Secondary outcomes		

1

Description

Changes in pulmonary artery pressure

Timepoint

At the beginning of the study and after 40 days of treatment

Method of measurement

Echocardiography

2

Description

Left ventricular end-diastolic volume

Timepoint

At the beginning of the study and after 40 days of treatment

Method of measurement

Echocardiography

Intervention groups

1

Description

Intervention group: Patients with Anterior ST-segment elevation acute myocardial infarction treated with primary PCI receiving Crataegus monogyna extract tablet (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 Anterior ST-segment elevation acute myocardial infarction treated with primary PCI receiving placebo tablet with the same shape and size twice a day for one 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 Hoveyze 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