Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Çrataegus 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)

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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
2023-10-07, 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

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 Randomaization.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.

Placebo
Used

Assignment
Parallel

Other design features

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
۹۱۳۷۹۱۳۳۱۶

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
Echocardioghraphy

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
Echocardioghraphy

2

Description
Left ventricular end-diastolic volume
Timepoint
At the beginning of the study and after 40 days of treatment
Method of measurement
Echocardioghraphy

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
Ghaeem 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, University Street, Mashhad
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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
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Person responsible for scientific inquiries

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Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr. Vafa Baradaran Rahimi

Position
Assistant professor

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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