Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the Effect of Consuming Tablets Containing Rosehip Fruit Alcoholic Extract on Pain Severity in Patients with Chronic Coronary Syndrome

Protocol summary

Study aim
Effect of Rosehip (1 gram daily for two months) on Pain Severity in Patients with Chronic Coronary Syndrome

Design
Double-blinded randomized controlled clinical trial with parallel groups, phase 3 on 30 patients. For randomization, the permutation block method was used using the www.randomization.com website.

Settings and conduct
The study group consists of outpatients diagnosed with chronic coronary syndrome who have met the inclusion and exclusion criteria for the study and are using medication or placebo at home for 2 months. At the beginning and after 2 months of using medication or placebo, patients are evaluated in terms of exercise test parameters at Dr. Dastani's office and the hospital. Patients and evaluators are blinded to the type of medication and placebo group.

Participants/Inclusion and exclusion criteria
Adult patients diagnosed with chronic coronary syndrome and without organ dysfunction

Intervention groups
In the treatment group, tablets containing 500 mg of hydroalcoholic extract of the rose hip, 2 times a day for 2 months will be added to the standard treatment regimen of slow coronary artery flow including ACEIS / ARBS, beta-blockers, aspirin and atorvastatin and nitrates. Placebo tablets will be used in the control group.

Main outcome variables
Individual information, history of previous illnesses, and medications used by the patient will be recorded at the beginning of the study. The primary measurable outcomes of the study are: total exercise time tolerance, time to onset of angina symptoms, electrocardiographic changes, double product, and Duke treadmill score.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120520009801N15**
Registration date: **2025-06-08, 1404/03/18**
Registration timing: **prospective**

Last update: **2025-06-08, 1404/03/18**
Update count: **0**

Registration date
2025-06-08, 1404/03/18

Registrant information

Name
Amir Hooshang Mohammadpour

Name of organization / entity
Mashhad University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 51 1882 3255

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mohamadpoorah@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-06-22, 1404/04/01

Expected recruitment end date
2025-12-22, 1404/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the Effect of Consuming Tablets Containing Rosehip Fruit Alcoholic Extract on Pain Severity in Patients with Chronic Coronary Syndrome

Public title
Effect of rosehip on chronic coronary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of Chronic Stable Angina Based on Clinical and Laboratory Parameters Obtaining Informed Consent from the Patient or Patient's Companion Absence of contraindications for exercise testing

Exclusion criteria:
Conditions that may compromise the electrocardiogram (ECG) or exercise test interpretation Congestive heart failure functional class III or IV History of acute coronary syndrome Any method of coronary revascularization within two months of enrollment Pregnancy or breastfeeding Renal insufficiency (GFR < 60 ml/min) Liver failure (child pugh score B or C)

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The method used to generate a random allocation sequence with a guarantee of equal allocation of individuals to the two groups is a permutation block created using the website www.randomization.com. With the explanation that each block has 4 members and the shape of the blocks is as follows: [AABB], [ABAB], [ABBA], [BABA], [BBAA], [BAAB] Code A belongs to the intervention group and code B belongs to the control group. Therefore, 12 quadruple blocks were randomly generated by the site and patients were assigned to two study groups based on the sequence obtained from the above blocks

Blinding (investigator's opinion)
Double blinded

Blinding description
The allocation concealment method is using opaque sealed envelopes with random sequences obtained from the random allocation step. The codes are given to the researcher present in the hospital. This researcher is fully aware of the type of codes. Medications are also given to him on the basis of the number (A or B) and he is fully aware of which drug or placebo. At the end of study, the evaluator (physician) who does not know which drug the patient has received and is aware only of the assigned code, performs the relevant evaluations and after registration, the results are given to the person who performs data analysis.

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
Vice Chancellor for Research and Technology, Third floor of Ghoreshi building, Next to Hoveyzeh Cinema, Daneshgah Street, Mashhad

City
mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2025-04-26, 1404/02/06

Ethics committee reference number
IR.MUMS.REC.1404.040

Health conditions studied

1

Description of health condition studied
chronic coronary syndrome

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Total duration of exercise test capacity

Timepoint
At baseline and two months after intervention

Method of measurement
Exercise test system

2

Description
Time to onset of angina
Timepoint
At baseline and two months after intervention
Method of measurement
Exercise test system

3

Description
Electrocardiographic changes
Timepoint
At baseline and two months after intervention
Method of measurement
Exercise test system

4

Description
Double product
Timepoint
At baseline and two months after intervention
Method of measurement
Exercise test system

5

Description
Duke score
Timepoint
At baseline and two months after intervention
Method of measurement
Exercise test system

Secondary outcomes

1

Description
Blood pressure
Timepoint
At baseline and two months after intervention
Method of measurement
Manometer

2

Description
Heart rate
Timepoint
At baseline and two months after intervention
Method of measurement
Exercise test system

3

Description
Lipid profile
Timepoint
At baseline and two months after intervention
Method of measurement
Blood test

4

Description
Complete blood count(CBC)
Timepoint
At baseline and two months after intervention
Method of measurement
Blood test

5

Description
Fasting blood sugar
Timepoint
At baseline and two months after intervention
Method of measurement
Blood test

6

Description
Liver function test
Timepoint
At baseline and two months after intervention
Method of measurement
Blood test

7

Description
Kidney function profile
Timepoint
At baseline and two months after intervention
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: tablets containing 500 mg of hydroalcoholic extract of rose hip prepared in the pharmacognosy and pharmaceutical laboratory of Mashhad Faculty of Pharmacy, 2 tablets daily oral for 2 months
Category
Treatment - Drugs

2

Description
Control group: Placebo tablets prepared in the pharmaceutical laboratory of the Mashhad Faculty of Pharmacy, 2 tablets daily oral for 2 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem hospital
Full name of responsible person
Mostafa Dastani
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9176699199
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2

Recruitment center
Name of recruitment center
Dr. Mustafa Dasanti's office
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
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Vice Chancellor for Research and Technology., third floor of Ghoreshi building., next to Hoveyzeh Cinema., University Street., Mashhad
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9138813944
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+98 51 3841 1538
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tafaghodiM@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
Amir Hooshang Mohammadpour
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long
starting 6 months after publication

To whom data/document is available
People working in academic institutions

Under which criteria data/document could be used
The use of data is unimpeded by mentioning the source.

From where data/document is obtainable
Dr. AmirHoushang Mohamadpour Mail: mohamadpoorah@mums.ac.ir Phone: 09153162909

What processes are involved for a request to access data/document
Reply to email within a maximum of one week

Comments