

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effects of Hesperidin supplementation on metabolic profile, stress oxidative and inflammatory markers (P-selectin, ox-LDL, hs-CRP) and paraxonase 1 in post myocardial infarction patients

Protocol summary

Summary

This study was designed to evaluate the effects of hesperidin supplementation on metabolic factors, serum levels of inflammatory markers and oxidative stress (P-selectin, ox-LDL, hs-CRP) and paraoxonase 1 in patients with myocardial infarction. This study is a double blind randomized clinical trial in 80 patients 70-30 who are with MI symptoms According to to diagnosis of profession . Participants will be divided into two groups (intervention group:40 Control group: 40.The intervention group consumed hesperidin supplements at a dose of 200 mg per day with one of the main meals for 12 weeks and The control group consumed a placebo capsule daily, who do the same shape and color supplements of hesperidin, but contains 200 mg starch for 12 weeks.Asked everyone to continue their normal diet and not to use any vitamin supplements during the study or drinks rich in flavonoids . At the beginning and end of the study, demographics, physical activity and a 3-day food record questionnaires will be completed. Anthropometric indices and blood pressure will be measured according to standard protocols. Metabolic factors, serum levels of inflammatory markers and oxidative stress measured at the beginning and end of the study by taking 10 cc of blood after 14-12 hours of fasting.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704099472N12**

Registration date: **2017-05-30, 1396/03/09**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-30, 1396/03/09

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Public Health School of Iran
University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of Hesperidin supplementation on metabolic profile, stress oxidative and inflammatory markers (P-selectin, ox-LDL, hs-CRP) and paraxonase 1 in post myocardial infarction patients

Public title

The effect of hesperidin supplement in the treatment of

myocardial infarction

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Risk of myocardial infarction, According to diagnosis of profession and clinical symptoms Including: 1. Chest pain for at least 20 minutes. 2. Clearly electrocardiographic changes. 3. Evidence of increased cardiac enzyme levels (According to : Depression treatment after myocardial infarction and long term risk of subsequent cardiovascular events and mortality: A randomized controlled trial article); The patient agreed to enter the study and willingness to cooperate and Signed informed consent; The use of any supplements, including: Antioxidant and vitamins during the last 3 months; The absence of any allergies (Gastrointestinal and skin) to Each type of antioxidant supplements and vitamins; MI Patients with up to 6 weeks after discharge ; 40-25: BMI; 30-70: Age; Not taking more than one blood orange or two of other citrus in a day Exclusion criteria: Lack of follow-up after discharge; Patient dissatisfaction or Not wanting to continue the cooperation of the patient for any reason ; The use of antioxidant supplements and vitamins and Q10 supplement; Find allergy symptoms at any time during the study; Suffering from Uncontrolled chronic diseases (Liver dysfunction, kidney failure, diabetes, etc.); Gastrointestinal disorders Compliance below the 80%; Taking antibiotics and catching infectious diseases No entry criteria: Taking more than 500 ml per day of drinks and food sources rich in flavonoids (Green tea, coffee, citrus juice, which is determined through a entry criteria questionnaire; Dont use of heparin and Varfarin; Unable to follow-up patient after discharge; Smoking and tobacco; Any allergies to any kind of vitamin supplements; Pregnancy and lactation; Suffering from any Uncontrolled metabolic disease

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Iran University of Medical Sciences

Street address

53/5000 Hemmat Highway, Besides Milad Tower Iran University of Medical Sciences

City

Tehran

Postal code

1449614535

Approval date

2017-01-16, 1395/10/27

Ethics committee reference number

IR.IUMS.REC.1395.9321323002

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

P-Selectin

Timepoint

Before intervention and three months after intervention

Method of measurement

Plasma samples

2

Description

Fasting blood glucose

Timepoint

Before intervention and three months after intervention

Method of measurement

Plasma samples

3

Description

triglyceride

Timepoint

Before intervention and three months after intervention

Method of measurement

Plasma samples

4

Description

total cholesterol

Timepoint

Before intervention and three months after intervention

Method of measurement

Plasma samples

5

Description

LDL cholesterol

Timepoint

Before intervention and three months after intervention

Method of measurement

formula

6

Description

HDL cholesterol

Timepoint

Before intervention and three months after intervention

Method of measurement

Plasma samples

7

Description

PON 1

Timepoint

Before intervention and three months after intervention

Method of measurement

Plasma samples

8

Description

hs-CRP

Timepoint

Before intervention and three months after intervention

Method of measurement

Plasma samples

9

Description

Diastolic pressure

Timepoint

Before intervention and three months after intervention

Method of measurement

Barometer

10

Description

Systolic pressure

Timepoint

Before intervention and three months after intervention

Method of measurement

Barometer

11

Description

OX-LDL

Timepoint

Before intervention and three months after intervention

Method of measurement

Plasma samples

12

Description

Conicity Index

Timepoint

Before intervention and three months after intervention

Method of measurement

formula

13

Description

Body composition

Timepoint

Before intervention and three months after intervention

Method of measurement

e-body instrument

Secondary outcomes

1

Description

Body mass Index

Timepoint

Before intervention and after intervention

Method of measurement

formula

2

Description

Anthropometric indices

Timepoint

Before intervention and after intervention

Method of measurement

Meters and scales

3

Description

physical activity

Timepoint

Before intervention and after intervention

Method of measurement

IPAQ questionnaire

4

Description

food intake

Timepoint

Before intervention and between and after intervention

Method of measurement

3 day 24 hour food recall

Intervention groups

1

Description

In the intervention group: patients in intervention group receive a 200 mg net hesperidin supplements daily for 12 weeks with the main meal.

Category

Treatment - Drugs

2

Description

In the control group: patients in control group receive a capsules similar to hesperidin supplements containing 200 mg starch daily for 12 weeks with the main meal.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital in Tehran

Full name of responsible person

Dr Mohammad Hosein Najafi

Street address

Tehran,Mulla Sadra Street, the intersection of Sheikh Bahai, hospital Baqiyatallah

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran university of medical science

Full name of responsible person

Dr Naheed aryaeeian

Street address

Tehran,Hemmat highway,besides Milad tower, Iran university of medical science

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran university of medical science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Vice President of Research of Iran university of medical science

Full name of responsible person

Dr mohammadreza Vafa

Position

PhD Nutrition Sciences

Other areas of specialty/work

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Full name of responsible person

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty