Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 symptomes 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
Country
Iran (Islamic Republic of)
Phone
+98 21 8670 4750
Email address
aryaeian.n@iums.ac.ir

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 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 tial 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 TowerIran 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 cholestrol
Timepoint
Before intervention and three months after intervention
Method of measurement
Plasma samples

5

Description
LDL cholestrol
Timepoint
Before intervention and three months after intervention
Method of measurement
formula

6

Description
HDL cholestrol
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
Street address
tehran,hemmat highway,besides milad tower,Vice President of Research of Iran university of medical science
City
tehran
Postal code
1449614535
Phone
+98 21 8670 4743
Fax
+98 21 8862 2707
Email
rezavafa@yahoo.comhttp://Vafa.m@iums.ac.ir
Web page address
http://www.iums.ac.ir/

Person responsible for scientific inquiries

Contact
Name of organization / entity
Vice President of Research of Iran university of medical science
Full name of responsible person
Dr naheed aryaeeian
Position
PhD Nutrition Sciences
Other areas of specialty/work
Street address
hemmat highway,besides milad tower,Vice President of Research of Iran university of medical science,
City
tehran
Postal code
1449614535
Phone
+98 21 8670 4750
Fax
+98 88622707
Email
nah_arya2002@yahoo.comhttp://Aryaeian.n@iums.ac.ir

Web page address
http://www.iums.ac.ir/

Person responsible for updating data

Contact

Name of organization / entity
Vice President of Research of Iran university of medical science

Full name of responsible person
zahra Booyani

Position
post Graduate student,public health in nutrition

Other areas of specialty/work

Street address
Tehran, Hemmat highway, Besides Milad Tower, Iran University of Medical Sciences

City
tehran

Postal code
1449614535

Phone
+98 21 8670 4750

Fax
+98 21 8862 2707

Email
Z_b137026@yahoo.com

Web page address
http://www.iums.ac.ir/

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