

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effect of Hesperidin supplementation on the serum levels of inflammatory markers (E-selectin, Interlukin 6, hs-CRP) and Adipocytokines (leptin and adiponectin) in patients with myocardial infarction

Protocol summary

Summary

A randomized, double-blind, placebo-controlled clinical trial was conducted to investigate the effects of 600 mg pure hesperidin supplements on the serum levels of inflammatory markers and adipocytokines in myocardial infarction patients. All subjects were asked for blood collection, evaluated of anthropometric indices and dietary intakes at the beginning of the present study. Next, 60 MI patients by randomized block allocation were divided into two groups (intervention: n=30, and control: n=30). For the subjects in the intervention group, one capsule included 600 mg pure hesperidin was provided to consume in the morning with breakfast every day for 4 weeks. On the other hand, the control group received on placebo capsule that was similar the color and shape of hesperidin capsule but included 600 mg starch, for 4 weeks. All subjects were instructed to continued their habitual diets and were taking no vitamin/mineral supplements or flavonoid-rich beverages during the study. They also were asked to take these supplements in the morning with breakfast. In the middle of study, dietary intakes were measured. In addition, Anthropometric indices and dietary intakes were evaluated at the end of the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012100210181N2**
Registration date: **2013-11-27, 1392/09/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-11-27, 1392/09/06

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2012-10-22, 1391/08/01

Expected recruitment end date

2013-01-19, 1391/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Hesperidin supplementation on the serum levels of inflammatory markers (E-selectin, Interlukin 6, hs-CRP) and Adipocytokines (leptin and adiponectin) in patients with myocardial infarction

Public title

Evaluation of the effect of Hesperidin supplementation in

patients with myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

The inclusion criteria were patients with myocardial infarction, being in the range of 40-65 years old, having body mass index (BMI) from 18.5-30 and patients satisfaction. Exclusion criteria included chronic disease (such as Hepatic disorders, Renal failure, diabetes, et.al.), Gastrointestinal disorders, major psychiatric disorder, taking antidepressants, absolute vegetarian diet, consumption of antioxidant and vitamin supplements at least 6 month before sampling, High consumption of flavonoid-rich beverages (including green tea, coffee, juice, et.al.), smoking, allergies to any vitamin supplements, lack of patient follow-up and lack of consent.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Postal code

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

ETH-569

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

IL-6

Timepoint

before intervention and after one month intervention

Method of measurement

plasma levels

2

Description

hs-CRP

Timepoint

before intervention and after one month intervention

Method of measurement

plasma levels

3

Description

leptin

Timepoint

before intervention and after one month intervention

Method of measurement

plasma levels

4

Description

adiponectin

Timepoint

before intervention and after one month intervention

Method of measurement

plasma levels

5

Description

e-selectin

Timepoint

before intervention and after one month intervention

Method of measurement

plasma levels

Secondary outcomes

1

Description

physical activity

Timepoint

before and end of intervention

Method of measurement

IPAQ questionnaire

2

Description

anthropometric indices

Timepoint

before and end of intervention

Method of measurement

meter and scale balance

3

Description

dietary assessment

Timepoint

before, middle and end of intervention

Method of measurement

The three-day, 24-hour food recall

Intervention groups

1

Description

For the subjects in the intervention group, one capsule included 600 mg pure hesperidin was provided to consume in the morning with breakfast every day for 4 weeks

Category

Treatment - Drugs

2

Description

the control group received on placebo capsule that was similar the color and shape of hesperidin capsule but included 600 mg starch, in the breakfast for 4 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital in Ahvaz

Full name of responsible person

Dr. Habib Heibar

Street address

Golestan, Golestan Hospital in Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nutrition and Metabolic Diseases Research Center in Ahvaz Jundishapur University of Medical sciences

Full name of responsible person

Dr. Majid Karandish

Street address

Ahvaz Jundishapur University of Medical sciences

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nutrition and Metabolic Diseases Research Center in Ahvaz Jundishapur University of Medical sciences

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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Fatemeh Haidari

Position

Ph.d of Nutrition

Other areas of specialty/work

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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