Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

The effect of quercetin supplement on inflammatory factors and quality of life in patients with myocardial infarction

Protocol summary

Study aim

The effect of quercetin supplement on inflammatory factors and quality of life in patients with myocardial infarction

Design

This study is a double-blind randomized clinical trial which will be done in patients with myocardial infarction who referred to the heart department of Rasoul-e-Akram Hospital in 2018-2019. Individuals who are willing to participate and enter the study, sign a written informed consent and enter the study. The duration of the study is 8 weeks, which is randomly assigned to 44 patients with myocardial infarction in quercetin supplement group and 44 patients with myocardial infarction in the placebo group. This study is in the third Phase of clinical trial.

Settings and conduct

In this study, patients with myocardial infarction referring to Hazrat Rasoul-e-Akram Hospital, who according to inclusion criteria and exclusion criteria, have the criteria to participate the study, would be asked to complete a written informed consent form. Individuals will be randomly assigned to receive intervention or placebo. Then, at the beginning and at the end of the study, 10 cc of fasting blood will be drawn. The level of inflammatory factors IL-6, TNF-α, hs-CRP and serum TAC levels will be measured. At the beginning and the end of the study, anthropometric measurments and personal information questionnaires, myocardial infarction dimensional assessment scale (MIDAS), physical activity, and 24-hour recall are filled through interview.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having the consent and willingness to participate in the study, Age range from 35 to 65 years, Passing 6 to 8 weeks after the first heart attack, Body mass index less than 30 kilogram/meter2 Exclusion criteria: smoking, alcohol consumption or narcotic use, taking vitamin, antioxidant or omega-3 supplements in the past 3 months, taking non-steroidal anti-inflammatory drugs in the past 3 months, having a history of chronic inflammation, kidney, liver and thyroid disease, The occurrence of any problem or sensitivity at any time during the study, non-compliance with treatment (less than 80% or less than 48 days), changes in physical activity, diet or changes in the type and dosage of the drug during the study, and Acute illness

Intervention groups

Quercetin group: 44 men and women with myocardial infarction, each receive a daily dose of 500 mmilligrams of quercetin supplement after meal for 8 weeks. Placebo group: 44 men and women with myocardial infarction, each receive a daily dose of 500 milligrams of placebo tablet (containing lactose, cellulose and starch), which looks like quercetin supplement, after meal for 8 weeks.

Main outcome variables

The primary outcoms of this study are inflammatory factors (hs-CRP and TNF-α).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090822002365N19**
Registration date: **2018-02-26, 1396/12/07**
Registration timing: **prospective**

Last update: **2018-02-26, 1396/12/07**
Update count: **0**

Registration date

2018-02-26, 1396/12/07

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4734

Email address

vafa.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of quercetin supplement on inflammatory factors and quality of life in patients with myocardial infarction

Public title

The effect of quercetin supplement on patients with myocardial infarction

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having the consent and willingness to participate in the study Age range from 35 to 65 years Passing 6 to 8 weeks after the first heart attack BMI< 30 Kg/m2

Exclusion criteria:

Smoking, alcohol consumption or narcotic use Taking vitamin, antioxidant or omega-3 supplements in the last 3 months Taking non-steroidal anti-inflammatory drugs over the past 3 months Suffering or having a history of chronic inflammation, kidney, liver and thyroid disease The occurrence of any problem or sensitivity at any time during the study Non-compliance with treatment (less than 80% or less than 48 days) Changes in physical activity, diet, or change in the type and dosage of the drug during the study and the occurrence of acute illness

Age

From **35 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

For randomization, the permuted block randomization will be used with quadruple blocks. According to the identified sample size of 88, 22 blocks will be produced by using the online site (www.sealedenvelope.com).

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to apply the concealment in the randomization process, unique codes, which is generated by the software, will be used on the drug boxes. By entering each individual into the study based on the produced sequence, the drug box in which the code is registered, will be assigned to the individual. During the research, the randomization list is held by the statistic consultant, and the participants, the project implementer and all those who participate in the measurement of the indicators will not be aware of the assigned groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Science

Street address

Hemmat Express way, Iran University of Medical Science

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2018-02-12, 1396/11/23

Ethics committee reference number

IR.IUMS.REC 1396.9511323005

Health conditions studied

1

Description of health condition studied

myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Tumor necrosis factor alpha (TNF-α)
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
The level of TNF-α in serum is with ELISA method

2

Description
High-sensitive C-reactive protein (hs-CRP)
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
The level of hs-CRP in serum with Immunoturbidimetry method

Secondary outcomes

1

Description
Interleukin 6 (IL-6)
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
The level of IL-6 in serum with ELISA method

2

Description
Total Antioxidant Capacity (TAC)
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
The level of TAC in serum with ELISA method

3

Description
Quality of life
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
Myocardial infarction dimensional assessment scale (MIDAS) questionnaire

4

Description
Systolic blood pressure
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
sphygmomanometer (mmHg)

5

Description
diastolic blood pressure
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
sphygmomanometer (mmHg)

6

Description
Body Mass Index (BMI)
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
body weight in kilograms divided by the square of the body height in meters (kg/m2)

7

Description
waist circumference
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
Midpoint between the lower margin of the last palpable rib and the top of the iliac crest

8

Description
Body fat percentage
Timepoint
At the baseline and after 8 weeks of intervention
Method of measurement
Body composition monitor scale

Intervention groups

1

Description
Intervention group: 44 men and women with myocardial infarction, each receive a daily dose of 500 milligrams of quercetin supplement after meal for 8 weeks.
Category
Treatment - Other

2

Description
Control group: 44 men and women with myocardial infarction, each receive a daily dose of 500 milligrams of placebo (containing lactose, cellulose and starch), which looks like to quercetin supplement, after meal for 8 weeks.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul-e-Akram Hospital

Full name of responsible person
Seyed Hashem Sezavar Seyedi Jandaghi
Street address
Hazrat Rasoul-e-Akram Hospital, Mansouri Ave, Niyayesh Ave, Sattarkhan Ave
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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 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
Iran University of Medical Sciences
Full name of responsible person
Mohammadreza Vafa
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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Only a part of the data will be shared, such as primary outcomes and Etc.

When the data will become available and for how long

The access period will be 6 months after the publication of the results.

To whom data/document is available

The obtained data from current study will be available only for researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Six months after the publication of this study papers, the obtained data will be available to the applicant researchers for further analysis.

From where data/document is obtainable

Applicants can be contacted with corresponding author by e-mail or postal address to receive the requested data. Postal address: Nutrition Department, School of health, Iran University of Medical Science, Hemmat Expressway, Tehran Phone Number: 0098 2186704743 E-mail: rezavafa@yahoo.com

What processes are involved for a request to access data/document

Applicants will be able to access the obtained data from current study by sending an email to the corresponding author up to one week.

Comments