

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Effects of saffron aqueous extract and its main carotenoids (crocin and crocetin) on expression of some genes involved in atherosclerosis in peripheral blood mononuclear cells of patients with coronary heart disease

Protocol summary

Summary

Background: Coronary artery occlusion is the main cause of myocardial infarction and death in Iran. Saffron is a native spice which is consumed abundantly in our country. Saffron and its two main carotenoids; crocin and crocetin have strong antioxidant capacity. They can also prevent or delay atherosclerosis plaque formation through different signaling pathways so improve cardiovascular health. Objectives and main outcomes: The aim of this study is to investigate the effects of saffron aqueous extract, crocin and crocetin on expression of some genes involved in the plaque formation including sirtuin-1, AMPK, NF-kappa B, MCP-1 in peripheral blood mononuclear cells, variables of lipid profile. Design, setting and conduct: It is an eight weeks double blind clinical trial conducted on 60 patients from Shahid Madani hospital. Patients were randomly divided into four groups. The questionnaires related to general information, the three-day food record, appetite levels, anthropometric measurements and quality of life will be completed. For biochemical tests, 20 ml blood will be collected after overnight fasting, at baseline and at the end of the study. Major eligibility criteria: Any overweight and obese 40 to 65 years old patients with coronary artery disease could participate. Intervention: The first group will receive two capsules containing 15 mg of saffron extract, the second group will receive two capsules containing 15 mg crocin, the third will get capsules contain 5 mg crocetin twice daily and the fourth group will receive placebo

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201512102017N26**

Registration date: **2016-01-17, 1394/10/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-01-17, 1394/10/27

Registrant information

Name

Alireza Ostadrahimi

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for Research, Tabriz University of Medical Sciences, Nutrition Research Center

Expected recruitment start date

2016-01-20, 1394/10/30

Expected recruitment end date

2016-11-20, 1395/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of saffron aqueous extract and its main carotenoids (crocin and crocetin) on expression of some genes involved in atherosclerosis in peripheral blood mononuclear cells of patients with coronary heart disease

Public title
Effects of saffron extract and its two main carotenoids (crocin, crocetin) on coronary heart disease

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: overweight and obese patients with coronary heart disease; lack of cancers; autoimmune diseases and infectious; lack of allergy; no history of antioxidant supplements during the past six months; willingness to participate in this research project
Exclusion criteria: Any MI; Catching any infectious disease during the study; Menopause; pregnancy and lactation; expose with any side effects during the study; Unwillingness to continue participation in the study

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

Gender
Both

Phase
2

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

Ethics Committee Tabriz University of Medical Sciences

Street address

Third floor, Central building(2), Tabriz University of Medical Sciences, Golgasht street

City

Tabriz

Postal code

Approval date

2015-11-23, 1394/09/02

Ethics committee reference number

TBZMED.REC.1394.739

Health conditions studied

1

Description of health condition studied

Coronary Heart Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Sirtuin-1 expression

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

real time-PCR

2

Description

AMPK expression

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

real time-PCR

3

Description

NF-kappa B expression

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

real time-PCR

4

Description

MCP-1 expression

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

real time-PCR

5

Description

plasma levels of MCP-1

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

elisa (ng/ml)

6

Description

lipid profile variables

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

measurements of TC, LDL-c, HDL-c, TG by autoanalyzer

Secondary outcomes

1

Description

quality of life score

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

Mac new quality of life questionnaire

2

Description

food intake

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

three days food records

3

Description

appetite levels

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

visual analogue scale

4

Description

anthropometric indices

Timepoint

at baseline and after 2 months at the end of study

Method of measurement

measurements of height, waist and hip circumference with tape measure , weight with Seca scale

Intervention groups

1

Description

crocin capsule, 15 mg, twice daily

Category

Treatment - Other

2

Description

saffron aqueous extract capsule, 15 mg, twice daily

Category

Treatment - Other

3

Description

croctin capsule, 5 mg, twice daily

Category

Treatment - Other

4

Description

placebo, twice daily

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Medical Research Training Center

Full name of responsible person

Dr Mohammadreza Taban Sadeghi

Street address

Daneshgah Street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research of Tabriz University of Medical Sciences, Nutrition Research Center

Full name of responsible person

prof. Alireza Ostadrahimi

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Third floor, Central building(2), Tabriz University of Medical Sciences, Golgasht avenue

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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

Vice-chancellor for Research of Tabriz University of Medical Sciences, Nutrition Research Center

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

Tabriz University of Medical Sciences

Full name of responsible person

Nasim Abedimanesh

Position

Ph. D. candidate in Nutrition

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Fax

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