

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of vitamin E and C supplements on risk factors of coronary artery disease (CAD) in patients with coronary heart disease

Protocol summary

Study aim

Determination of the effect of vitamin E and C supplements on risk factors of coronary artery disease (CAD) in patients with coronary heart disease

Design

In this clinical trial with a factorial design, the patients will be allocated to four groups of control, vitamin C, vitamin E and combination by permutation blocks. The groups will be matched in terms of confounding variables such as occupation, education, age, gender, diabetes, physical activity, drugs that affect blood lipids and glucose, blood lipids and glucose levels, blood pressure, BMI and CRP.

Settings and conduct

The research area will be the specialized heart clinic of Jawad Al-Aimeh and Razavi hospitals in Mashhad. After obtaining informed consent from patients, explaining the goals of the plan for them, if they have inclusion criteria, after 15 minutes of rest, the systolic and diastolic blood pressure of the patient and then the height and weight will be measured. Then everyone after 8-12 hours of fasting during the night and a blood sample to check FBS, lipid profile and CRP will be sent to the laboratory. After grouping the patients and implementation of the intervention, again, the outcome variables will be measured in all patients at the end of the study.

Participants/Inclusion and exclusion criteria

All patients who are willing to participate in the study have entry requirements in terms of inclusion criteria.

Intervention groups

In the control group, no supplement will be given and only routine care will be provided. In other groups, in addition to routine care, separately in group of vitamin C, 1,000 mg of vitamin C for 10 weeks, in vitamin E, 600 mg of vitamin E for 10 weeks, in combination, daily 1000 mg of vitamin C and 600 mg of vitamin E for 10 weeks will be prescribed by your doctor.

Main outcome variables

Systolic and diastolic blood pressure, lipid profiles, FBS,

BMI and CRP

General information

Reason for update

Acronym

مطالعه بیماری های عروق کرونر

IRCT registration information

IRCT registration number: **IRCT20180804040688N1**

Registration date: **2018-08-15, 1397/05/24**

Registration timing: **prospective**

Last update: **2018-08-15, 1397/05/24**

Update count: **0**

Registration date

2018-08-15, 1397/05/24

Registrant information

Name

Sajad Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3366 4228

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin E and C supplements on risk factors of coronary artery disease (CAD) in patients with coronary heart disease

Public title

The effect of vitamin E and C on risk factors of coronary artery disease (CAD)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclination to participate in research Certification of physician to receive vitamins E and C Age 18 to 50 years old Acceptable listening, speaking and consciousness to answer the questions Waist circumference is more than 102 cm in men and more than 88 cm in women Fasting triglyceride equal to or greater than 150 mg/dl HDL less than 40 mg/dl Systolic blood pressure equal to or greater than 135 mm Hg Fasting glucose is greater than or equal to 110 mg/dl

Exclusion criteria:

Not pregnant Do Not taking corticosteroids and contraceptives Lack of underlying diseases (such as kidney and liver failure, thyroid dysfunction, malignancy, mental, autoimmune and infectious diseases) Lack of specific medical conditions requires as a change in diet and exercise program Lack of insulin treatment The need for surgery during the study Cancellation request of the patient Incidence of unwanted side effects Irregular consumption of supplements

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: permutation block Random unit: Individual Randomization Tool: Random Numbers

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Gonabad University of Medical Sciences

Street address

Research Deputy in Gonabad University of Medical Sciences, next to the Asian Road, Gonabad, Khorasan Razavi, Iran.

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2018-08-04, 1397/05/13

Ethics committee reference number

IR.GMU.REC.1397.064

Health conditions studied

1

Description of health condition studied

Coronary artery disease (CAD)

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

Before and after the intervention

Method of measurement

Mercury sphygmomanometer

2

Description

Lipid profiles

Timepoint

Before and after the intervention

Method of measurement

Laboratory instruments

3

Description

Fasting blood sugar

Timepoint

Before and after the intervention

Method of measurement

Laboratory instruments

4

Description

Body mass index (BMI)

Timepoint

Before and after the intervention

Method of measurement

Weight (kilograms) / square height (meter)

5

Description

C-reactive protein (CRP)

Timepoint

Before and after the intervention

Method of measurement

Laboratory instruments

Secondary outcomes

empty

Intervention groups

1

Description

Vitamin E Group: This group only consumes vitamin E supplement of 600 mg daily for 10 weeks.

Category

Treatment - Drugs

2

Description

Vitamin C Group: This group only consumes vitamin C supplement of 1000 mg daily for 10 weeks.

Category

Treatment - Drugs

3

Description

Combination Group: This group consumes vitamin E of 600 mg and vitamin C of 1000 mg supplements daily for 10 weeks.

Category

Treatment - Drugs

4

Description

Control group: This group will not receive any supplement.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Razavi hospital in Mashhad

Full name of responsible person

Sajjad Rezaei

Street address

Razavi Hospital, after Ghaem Bridge, Freedom Highway, Mashhad, Khorasan Razavi, Iran.

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Razavi Khorasan

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2

Recruitment center**Name of recruitment center**

Jawad Al-Aimeh hospital in Mashhad

Full name of responsible person

Sajjad Rezaei

Street address

Jawad Al-Aimeh hospital, Honarestan three way, Vakil Abad boulevard, Mashhad, Khorasan Razavi, Iran.

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Gonabad University of Medical Sciences

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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Sajjad Rezaei

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Surgical thecnology

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

Samane Najafi

Position

Lecturer, Faculty member, School of Nursing, Gonabad University of Medical Sciences.

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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Position

Student

Latest degree

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Other areas of specialty/work

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Street address

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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

Potential data will be shared after unidentifiable individuals.

When the data will become available and for how long

Get started 8 months after the publication of results

To whom data/document is available

The researcher on academic institutions

Under which criteria data/document could be used

The information should not be changed.

From where data/document is obtainable

E-mail Sajjad Rezaei:

sajadrezaeisturgical009@gmail.com E-mail Samane

Najafi: s.najafi2012@yahoo.com

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

The E-mail to the given address and provide sufficient and acceptable information. Information will be given if data is acceptable.

Comments