Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

sajadrezaeistusurgical009@gmail.com

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.
City
Mashhad
Province
Razavi Khorasan
Postal code
9198613636
Phone
+98 51 3666 8888
Email
info@razavihospital.com

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

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No. 4, 10 Golriz Ave., 10 sarakhs Ave., Mashhad, Khorasan Razavi, Iran.

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sajadrezaeistusurgical009@gmail.com

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

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

No. 4, 10 Golriz Ave., 10 sarakhs Ave., Mashhad, Khorasan Razavi, Iran.

City

Mashhad

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Postal code

9167911713

Phone

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Email

sajadrezaeistusurgical009@gmail.com

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: sajadrezaeistusurgical009@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