

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

The combined effect of vitamins E and C supplementation on lipid profile in elderly residents in Isfahan

Protocol summary

Summary

Our objective in this study is assessing the combined effect of vitamin E and C supplementation on lipid profile in elderly residents in Isfahan. This double-blind intervention study was conducted on 210 participants aged 60 -75 years old. Exclusion criteria: The lack of a liver disorder, renal failure and mal absorption, any kind of cancer, or any illness that may interfere with the absorption of antioxidants, taking medications that could seriously disrupt lipid metabolism, those who at baseline diagnosed hyperlipidemic of course with The experiment was done, and Did not receive a medication to control it and required medication. They were divided into intervention and control groups based on sex and age. Intervention group take vitamin E (300 mg/day) and vitamin C (400 mg/day) and the control group take placebo for one year. At baseline of study, background information was collected through general questionnaire and dietary intake was collected through three-day food records every two months. Before intervention, after 6 months and at the end of the study triglyceride, total cholesterol, and high density lipoprotein and low density lipoprotein were measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052517831N1**

Registration date: **2014-06-11, 1393/03/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-06-11, 1393/03/21

Registrant information

Name

Mahsa Malekahmadi

Name of organization / entity

School of Nutritional Sciences and Dietetics, Tehran
University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

tehran university of medical science

Expected recruitment start date

2010-01-21, 1388/11/01

Expected recruitment end date

2011-07-23, 1390/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The combined effect of vitamins E and C supplementation on lipid profile in elderly residents in Isfahan

Public title

effect of vitamins E and C on lipid profile in elderly

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age between 60 to 75 years; literacy rate higher than fifth grade; Exclusion criteria: The lack of a liver disorder, renal failure and mal absorption, any kind of cancer, or any illness that may interfere with the

absorption of antioxidants; Smoking, tobacco and drug abuse; taking Vitamin C and E supplementation before entering the study; taking medications that could seriously disrupt lipid metabolism, such as fibrates, nicotinic acid, glucocorticoids; those who at baseline diagnosed hyperlipidemic of course with The experiment was done, and did not receive a medication to control it and required medication; severe disability

Age

From **28 years** old to **13 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **210**

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

Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Ghods street, Keshavarz square

City

Tehran

Postal code

Approval date

2013-01-08, 1391/10/19

Ethics committee reference number

2044379051

Health conditions studied

1

Description of health condition studied

Pure hypercholesterolaemia

ICD-10 code

E78.0

ICD-10 code description

Familial hypercholesterolaemiaFredrickson hyperlipoproteinaemia, type IIaHyperbetalipoproteinaemiaHyperlipidaemia, group ALow-density-lipoprotein-type [LDL] hyperlipoproteinaemia

2

Description of health condition studied

Mixed hyperlipidaemia

ICD-10 code

E78.2

ICD-10 code description

Broad- or floating-betalipoproteinaemiaFredrickson hyperlipoproteinaemia, type IIb or IIIHyperbetalipoproteinaemia with prebetalipoproteinaemiaHypercholesterolaemia with endogenous hyperglyceridaemiaHyperlipidaemia, group CTubero-eruptive xanthomaXanthoma

3

Description of health condition studied

Other hyperlipidaemia

ICD-10 code

E78.4

ICD-10 code description

Familial combined hyperlipidaemia

4

Description of health condition studied

Lipoprotein deficiency

ICD-10 code

E78.6

ICD-10 code description

AbetalipoproteinaemiaHigh-density lipoprotein deficiencyHypoalphalipoproteinaemiaHypobetalipoproteinaemia (familial)Lecithin cholesterol acyltransferase deficiencyTangier disease

5

Description of health condition studied

Hyperlipidaemia, unspecified

ICD-10 code

E78.5

ICD-10 code description

Primary outcomes

1

Description

total cholestrol

Timepoint

at baseline, after 6 mounth, after 1 year

Method of measurement

enzimatically- colorimetry

2

Description

LDL

Timepoint

at baseline, after 6 month, after 1 year

Method of measurement

enzimatically- colorimetry

3

Description

HDL

Timepoint

at baseline, after 6 month, after 1 year

Method of measurement

enzimatically- colorimetry

4

Description

TG

Timepoint

at baseline, after 6 month, after 1 year

Method of measurement

enzimatically- colorimetry

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group, daily received 300 mg of vitamin E (alfa-Tocopheryle Acetate) (ZAKARIYAYE RAZI manufacturer company), Which is exactly equal to 300 IU, and 400 mg of vitamin C (ascorbic acid)) OSVEH manufacturer company) for one year.

Category

Other

2

Description

control group, received 2 placebo (A product in terms of physical and chemical properties is quiet similar to C and E vitamins) for one year.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hashtbehesht laboratory

Full name of responsible person

Mahsa Malekahmadi

Street address

Hashtbehesht laboratory, eastern Hashtbehesht avenue

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ahmad Rezaei

Street address

Tehran University of Medical Sciences, Ghods street, Keshavarz square

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Amir Mansour Alavi

Position

phd/assistant

Other areas of specialty/work

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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