

# 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)

##### Phone

+98 913 125 0467

##### Email address

m-malekahmadi@razi.tums.ac.ir

##### 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**

**Street address**

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**Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahsa Malekahmadi

**Position**

phd/assistant

**Other areas of specialty/work**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahsa Malekahmadi

**Position**

student

**Other areas of specialty/work**

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00

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mahsa\_malekahmadi@yahoo.com

**Web page address**

## **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*