Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effect of vitamin E supplement on serum systemic and vascular inflammatory markers and lipids in hemodialysis patients

Protocol summary

Summary

1) Objectives: Main objectives: Effect of vitamin E supplement on serum systemic and vascular inflammatory markers and lipids in hemodialysis patients Proprietary objectives: 1- Determining the mean of variations like sex, height, age at baseline, weight, body mass index, total energy, total protein, fiber, total fat, saturated fatty acids, mono and poly unsaturated fatty acids, cholesterol, vitamin E and C in diet, in addition serum triglycerides, total cholesterol, low density lipoprotein cholesterol, high density lipoprotein cholesterol, high sensitive c reactive protein in baseline and the end of the study in both groups of patients (vitamin E and placebo) 2- The effect of vitamin E in lipid profile (total cholesterol, triglycerides, low density lipoprotein cholesterol, high density lipoprotein cholesterol levels) 3- The effect of vitamin E on serum systemic and vascular inflammatory markers (high sensitive c reactive protein, vascular cell adhesion protein 1, intercellular adhesion molecule 1, Interleukin 6) 4- Determination of serum concentration of Interleukin 6, vascular cell adhesion protein 1, intercellular adhesion molecule 1 and lipid profile at baseline and the end of the study in two hemodialysis patients groups (vitamin E and placebo) 5- Compare the quality of confounding variables like sex, age, smoking, type of dialysis filter, diabetes, vitamin E and C supplementation, gemfibrozil drug and statin group drugs between both groups of patients Practical objective: Find effective therapies with fewer side effects for the control of systemic and vascular inflammatory markers and lipids in hemodialysis patients 2) Design: - Study groups: one control group and one intervention group - Trial phase: 2 - Sample size : 44 patients. - Blinding: Blinding for patients and researchers groups - randomization: randomized clinical trial, randomization by stratified blocked randomization method. 3) Setting and conduct: - At the beginning of study, before starting dialysis, blood samples are going to be taken after12 to 14 hours fasting - In both men and women vitamin E and placebo are going to be given in intervention and control groups respectively for 10 weeks. - Fill out 24 hours recall questionnaire in 1th, 5th and 10th weeks - Tacking blood samples again at the end of the study 4) Inclusion criteria: - Passing at least one year of dialysis - Dialysis at least twice a week Exclusion criteria: - Supplementation with omega3 and antioxidant vitamins, Taking glucocorticoids, non-steroidal anti-inflammatory, thyroxine and warfarin drugs - Not taking supplements more than 10 percent in any pursuit 5) Intervention: In both men and women 3 soft gels of 200IU vitamin E in the intervention group and 3 placebo in the control group will be given daily with main meals for 10 weeks 6) Primary outcome measure: Serum Triglycerides Total Cholesterol Low Density Lipoprotein Cholesterol High Density Lipoprotein Cholesterol High Sensitive C Reactive Protein Vascular Cell Adhesion Protein 1 Intercellular Adhesion Molecule 1 Interleukin 6

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020232367N1**
Registration date: **2017-04-14, 1396/01/25**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-14, 1396/01/25

Registrant information

Name

Hossien Imani

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Governmental organization (Tehran University of Medical Science)

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of vitamin E supplement on serum systemic and vascular inflammatory markers and lipids in hemodialysis patients

Public title

Effect of vitamin E supplementation on complications in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged between 20 and 60 years; Passing at least one year of dialysis; Dialysis at least twice a week; Inclination to participate in this study
Exclusion criteria: Pregnancy; Infectious, inflammatory and cardiovascular disease, thyroid gland disorders, thrombocytopenia and nutritional support (enteral and parenteral nutrition); Supplementation with omega3 and antioxidant vitamins; Taking glucocorticoids, non-steroidal anti-inflammatory, thyroxine and warfarin drugs
Exclusion criteria: Unwillingness to cooperate; Kidney transplant; Not taking supplements more than 10 percent in any pursuit; Death

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

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

Ethic Committee Tehran University of Medical Sciences

Street address

No 605 room, Sixth floor, Central building of Tehran University of Medical Sciences, Keshavarz boulevard, Ghods street, Tehran

City

Tehran

Postal code

141556117

Approval date

2016-11-06, 1395/08/16

Ethics committee reference number

IR.TUMS.VCR.REC.1395.946

Health conditions studied

1

Description of health condition studied

Chronic Kidney Disease trearment by hemodialysis

ICD-10 code

Z48

ICD-10 code description

Preparatory care for dialysis

Primary outcomes

1

Description

Serum Triglycerides

Timepoint

Before and after of intervention

Method of measurement

Enzymatic method with autoanalyzer- mg/dl

2

Description

Serum Total cholestrol

Timepoint

Before and after of intervention

Method of measurement

Enzymatic method with autoanalyzer- mg/dl

3

Description
Serum Low Density Lipoprotein Cholestrol (LDL-C)
Timepoint
Before and after of intervention
Method of measurement
Calculate according to fridval formula - mg/dl

4

Description
Serum High Density Lipoprotein Cholestrol (HDL-C)
Timepoint
Before and after of intervention
Method of measurement
Enzymatic method with autoanalyzer- mg/dl

5

Description
Serum Intercellular Adhision Molecule 1 (ICAM-1)
Timepoint
Before and after of intervention
Method of measurement
Enzymatic method with autoanalyzer- ng/ml

6

Description
Serum Vascular Cell Adhesion Molecule 1 (VCAM-1)
Timepoint
Before and after of intervention
Method of measurement
ELISA test - ng/ml

7

Description
Serum high-sensitivity C-reactive protein (hs-CRP)
Timepoint
Before and after of intervention
Method of measurement
ELISA test - mg/l

8

Description
Serum Interleukin 6 (IL-6)
Timepoint
Before and after of intervention
Method of measurement
ELISA test - pg/l

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 200 IU oral vitamin E soft gel three times in day with breakfast, lunch and dinner meals for 10 weeks
Category
Treatment - Drugs

2

Description
Control group: Oral vitamin E placebo three times in day with breakfast, lunch and dinner meals for 10 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Labbafinezhad Hospital
Full name of responsible person
Shiva Samavat
Street address
9th Boostan, Pasdaran street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for researc, Tehran University of Medical Sciences
Full name of responsible person
Dr. Hossein Imani
Street address
6th floor, Central Organization of University, Ghods street, Keshavarz boulevard, Tehran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for researc, 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, Departmant of Nutrition and Dietetic

Full name of responsible person
Nasim Pirhadi

Position
Master of Science Student in Puplic Heaith

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