

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of omega-3 fatty acid plus vitamin E supplementation on metabolic profiles, inflammatory factors and biomarkers of oxidative stress in Hemodialysis patients

Protocol summary

Study aim

Objective: The aim of this study is to determine the effects of omega-3 fatty acid and vitamin E co-supplementation on metabolic profiles, inflammatory factors and biomarkers of oxidative stress in Hemodialysis patients.

Design

Study design: randomized double-blind placebo-controlled trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Among diabetic hemodialysis patients referred to Akhavan Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran, 120 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Supplements and placebos are similar in shape and size. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Patients aged 18-80 years with Hemodialysis status. Exclusion Criteria: Pregnant, taking antioxidant supplements or immunosuppressive medications within 3 months prior to enrollment.

Intervention groups

Intervention group: Omega-3 pearl and vitamin E pearl, 1250 mg and 400 IU, daily, for 12 weeks orally.
Intervention group: Omega-3 pearl, 1250 mg, daily, for 12 weeks orally. Intervention group: Vitamin E pearl, 400 IU, daily, for 12 weeks orally. Control group: Placebo pearl, daily, for 12 weeks orally.

Main outcome variables

Outcomes: Malondialdehyde and SGA score (primary outcomes), and glycemic control, lipid profiles, biomarkers of inflammation and oxidative stress

(secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Due to an error, the request for an update in our website was conducted after paper published. However, the revisions were accordance with either the original approved proposal or with coordination with Vice Chancellor of Research at the University.

Acronym

IRCT registration information

IRCT registration number: **IRCT201410245623N28**
Registration date: **2014-10-26, 1393/08/04**
Registration timing: **retrospective**

Last update: **2019-11-03, 1398/08/12**

Update count: **1**

Registration date

2014-10-26, 1393/08/04

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kashan University of Medical Sciences

Expected recruitment start date

2014-08-02, 1393/05/11

Expected recruitment end date

2014-08-06, 1393/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 fatty acid plus vitamin E supplementation on metabolic profiles, inflammatory factors and biomarkers of oxidative stress in Hemodialysis patients

Public title

Effect of supplementation in treatment of Hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients aged 18-80 years with Hemodialysis status

Exclusion criteria:

Pregnant Taking antioxidant supplements or immunosuppressive medications within 3 months prior to enrollment

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

Participants, investigators or the assessors of the outcomes are unaware of the study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Approval date

2014-08-01, 1393/05/10

Ethics committee reference number

P/29/5/1/3538

Health conditions studied**1****Description of health condition studied**

Hemodialysis

ICD-10 code

N18

ICD-10 code description

Chronic kidney disease

Primary outcomes**1****Description**

SGA score

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Calculation

2**Description**

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Secondary outcomes**1****Description**

Insulin

Timepoint

At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

2

Description
Insulin resistance
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Calculation using HOMA formula

3

Description
Triglycerides
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

4

Description
Total cholesterol
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

5

Description
HDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

6

Description
LDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

7

Description
VLDL
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement

Enzymatic kit

8

Description
FPG
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

9

Description
Total antioxidant
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

10

Description
Glutathione
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

11

Description
Nitric oxide
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Spectrophotometry

12

Description
Hs-CRP
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Elisa kit

13

Description
Creatinine
Timepoint
At the beginning of the study and after 12 weeks of intervention
Method of measurement
Enzymatic kit

14

Description

BUN

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

15

Description

Albumin

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

16

Description

TIBC

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Enzymatic kit

Intervention groups

1

Description

Intervention group: Omega-3 pearl and vitamin E pearl, 1250 mg and 400 IU, daily, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Intervention group: Omega-3 pearl, 1250 mg, daily, for 12 weeks orally.

Category

Treatment - Drugs

3

Description

Intervention group: Vitamin E pearl, 400 IU, daily, for 12 weeks orally.

Category

Treatment - Drugs

4

Description

Control group: Placebo pearl, daily, for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akhavan Hospital

Full name of responsible person

Zatollah Asemi

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Shahid Rajaee Avenue, Kashan

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8115187159

Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholamali Hamidi

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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

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Zatollah Asemi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Latest degree

Ph.D.

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Person responsible for updating data

Contact

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Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available