Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
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+98 36 1534 3570
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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
Isfehan
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
Street address
Shahid Rajaee Avenue, Kashan
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Isfehan
Postal code
8115187159
Phone
+98 31 5546 3378
Email
asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholamali Hamidi
Street address
Ghotbe Ravandi Boulevard, Kashan
City
Kashan
Province
Isfehan
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8115187159
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Email
research@kaums.ac.ir
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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Person responsible for updating data

Contact

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Associate professor
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Ph.D.
Other areas of specialty/work
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asemi_r@yahoo.com
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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