Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating therapeutic effects of omega-3 fatty acids (eicosapentaenoic acid and docosahexaenoic acid) on anemia and nutritional status in hemodialysis patients with depression

Protocol summary

Summary

The purpose of this study is to evaluate the potential positive effects of omega-3 fatty acids on anemia and nutritional status in hemodialysis patients with depression. Inclusion criteria: Age more than 16 years old; Initiation of hemodialysis from 3 months ago (at least); Beck depression score equal to or more than 16; Post-dialysis body mass index between 20 and 30. Exclusion criteria: Active underlying chronic inflammatory diseases; Chronic infection and/or acute infection within last month; Asthma or Chronic obstructive pulmonary disease; Other psychiatric disorders; Hypothyroidism; High risk for bleeding; Ingestion of omega-3 supplements in the past 3 months; Intolerance or allergic reaction to fish oil; Ingestion of medications effective on inflammatory markers within the last six weeks. Fifty hemodialysis patients with Beck depression score of equal to or more than16 will be randomized to receive omega-3 fatty acids (1800 mg per day orally) or placebo for 4 months. Before the initiation of the study and at the end of month 4 of the study, pre-dialysis blood samples (10 milliliters) will be taken from all patients to measure serum hemoglobin, transferring, albumin, pre-albumin concentrations . Body mass index, mid arm circumference and Beck depression score will be evaluated at these times as well. The potential effects of omega-3 fatty acids on these laboratory and clinical parameters will be compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202203043N5**
Registration date: **2012-04-10, 1391/01/22**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2012-04-10, 1391/01/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-05-04, 1391/02/15

Expected recruitment end date

2013-05-05, 1392/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating therapeutic effects of omega-3 fatty acids (eicosapentaenoic acid and docosahexaenoic acid) on anemia and nutritional status in hemodialysis patients with depression

Public title

Evaluating therapeutic effects of omega-3 fatty acids on anemia and nutritional status in hemodialysis patients with depression

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age more than 16 years old; Thrice weekly hemodialysis from the last three months (at least); The patient's ability to understand and sign the consent form; Use of biocompatible hemodialysis membrane; Proper functioning of arteriovenus fistula or indwelling catheter; Beck depression score equal to or more than 16; Post-dialysis body mass index between 20 and 30 Exclusion Criteria: Pregnancy; Active, uncontrolled or severe chronic inflammatory disease (autoimmune diseases, active connective tissue diseases, malignancy, AIDS, hepatic and pulmonary diseases); Chronic infection or acute infection in a recent month; Life expectancy of less than 4 months; Asthma or Chronic obstructive pulmonary disease; Other concurrent Psychiatric disorders; Hypothyroidism; Hemoglubinopathies and other causes of anemia (other than iron deficiency); Simultaneous participation in other trials (Drug or Supplemental); History of medical (like MI or Strock) or surgical illness in the last three months; Malabsorption syndrome; Bleeding disorders (including coagulopathy) or high risk for bleeding; Diet change in a recent month; Consumption of omega-3 supplements in the past 3 months; Intolerance or allergy to fish oil; Use of drugs effective on inflammatory factors (like corticosteroides or other immunosuppressives, Non-steroidal antiinflammatory drugs, contraceptives, Pentoxifylline) in the past 6 weeks; Concurrent use of antidepressants, antipsychotics, antiepileptics (other than gabapentin), methyldopa, cimetidine and serotonergic agents (like triptans, tramadol, tryptophan and linezolid); Warfarin therapy ; Alcohol abuse and other materials that cause dependency

Age

From **16 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Research deputy of Tehran University of Medical Sciences

Street address

4th Floor, Central Organization of Tehran University of Medical Sciences, Qods Avenue, Keshavarz Boulevard Steet, Tehran, Iran

City

Tehran

Postal code

1417653761

Approval date

2012-02-27, 1390/12/08

Ethics committee reference number

91-01-33-17020

Health conditions studied

1

Description of health condition studied

Anemia

ICD-10 code

D63.8*

ICD-10 code description

Anaemia in other chronic diseases classified elsewhere

2

Description of health condition studied

Nutritional Status

ICD-10 code

E44

ICD-10 code description

Protein-energy malnutrition of moderate and mild degree

3

Description of health condition studied

Depression

ICD-10 code

F32

ICD-10 code description

Depressive episode

4

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

Primary outcomes

1

Description
Serum Albumin Level
Timepoint
Immediately before starting the intervention and immediately after intervention completion
Method of measurement
colorimetric method particularly the bromcresol green (BCG) assay

2

Description
Serum pre-albumin Level
Timepoint
Immediately before starting the intervention and immediately after intervention completion
Method of measurement
Eliza Kit

3

Description
Serum Transferrin Level
Timepoint
Immediately before starting the intervention and immediately after intervention completion
Method of measurement
Immunoturbidimetric assay

4

Description
Body Mass Index (BMI)
Timepoint
Immediately before starting the intervention and immediately after intervention completion
Method of measurement
Weight (Kg) divided by Height (m) square

5

Description
Mid-arm circumference
Timepoint
Immediately before starting the intervention and immediately after intervention completion
Method of measurement
By measuring tape

6

Description
Hemoglobin level
Timepoint
Immediately before starting the intervention, monthly and after intervention
Method of measurement
cyanmethemoglobin method (colorimeter, spectrophotometer)

Secondary outcomes

1

Description
Interleukin- 6
Timepoint
Immediately before starting the intervention and immediately after intervention completion
Method of measurement
Eliza Kit

2

Description
Serum Hepcidin level
Timepoint
Immediately before starting the intervention, three months after the intervention and after the completion of intervention
Method of measurement
Eliza Kit

3

Description
Required dose of iron in hemodialysis patients with depression
Timepoint
Immediately before starting the intervention and immediately after intervention
Method of measurement
Study of patient records and interview with the patient

4

Description
Required dose of erythropoietin in hemodialysis patients with depression
Timepoint
Immediately before starting the intervention and immediately after intervention
Method of measurement
Study of patient records and interview with the patient

5

Description
Serum Ferritin Level
Timepoint
Immediately before starting the intervention, three months after the intervention and after the completion of intervention
Method of measurement
antigen/latex-antibody reaction by the end-point method

6

Description
Serum Iron level
Timepoint
Immediately before starting the intervention, three months after the intervention and after the completion of

intervention

Method of measurement

colorimetric method

7

Description

Transferrin saturation

Timepoint

Immediately before starting the intervention, three months after the intervention and after the completion of intervention

Method of measurement

Product ratio of serum iron to total iron binding capacity in 100

8

Description

Tumor Necrosis Factor-a

Timepoint

Immediately before starting the intervention and immediately after intervention completion

Method of measurement

Eliza Kit

9

Description

Interleukin- 10

Timepoint

Immediately before starting the intervention and immediately after intervention completion

Method of measurement

Eliza Kit

10

Description

C-reactive protein

Timepoint

Immediately before starting the intervention and immediately after intervention completion

Method of measurement

latex-enhanced turbidimetric immunoassay method

11

Description

Depression

Timepoint

Immediately before starting the intervention and immediately after intervention completion

Method of measurement

Beck Depression Inventory

Intervention groups

1

Description

Intervention Group: Omega-3, 300 mg oral capsule, 2 capsules three times daily for 4 months

Category

Treatment - Drugs

2

Description

Control Group: Placebo, 300 mg oral capsule, 2 capsules three times daily for 4 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis ward of Imam Khomeini Hospital

Full name of responsible person

Dr. Afshin gharekhani, Clinical Pharmacy Resident

Street address

Hemodialysis ward, Imam Khomeini Hospital, Doctor Gharib Street, The end of Keshavarz Boulevard, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr, Akbar Fotouhi

Street address

School of Public Health / Epidemiology and Biostatistics, Tehran University of Medical Sciences, Tehran, Iran

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

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

2

Sponsor
Name of organization / entity
Zahravi Pharmaceutical Company
Full name of responsible person
Dr. Ferdows Nasirzadeh
Street address
No. 178, Hoveyzeh Gharbi St., Shahid Abdolhamid Saboonchi Ave., Shahid Dr. Beheshti Ave., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahravi Pharmaceutical Company
Proportion provided by this source
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

Person responsible for scientific inquiries

Contact
Name of organization / entity
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Person responsible for updating data

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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