

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 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 than 16 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

Name

Simin Dashti-Khavidaki

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

dashtis@sina.tums.ac.ir

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 arteriovenous 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; Hemoglobinopathies and other causes of anemia (other than iron deficiency); Simultaneous participation in other trials (Drug or Supplemental); History of medical (like MI or Stroke) 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 corticosteroids or other immunosuppressives, Non-steroidal antiinflammatory drugs, contraceptives, Pentoxifylline) in the past 6 weeks; Concurrent use of antidepressants, antipsychotics, antiepileptics (other than gabapentin), methyl dopa, 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- α

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

Sponsor**Name of organization / entity**

Zahravi Pharmaceutical Company

Full name of responsible person

Dr. Ferdows Nasirzadeh

Street address

No. 178, Hoveyze 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**

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Reza Khatami

Position

Associate Professor, Nephrologist

Other areas of specialty/work**Street address**

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

City

Tehran

Postal code

1419733141

Phone

+98 21 6119 2679

Fax

+98 21 6658 1568

Email

khatamis@sina.tums.ac.ir

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Faculty of Pharmacy, Tehran University of Medical Sciences

Full name of responsible person

Dr. Afshin Gharekhani

Position

Pharmacy Doctorate (Pharm D)/ Resident in Clinical Pharmacy

Other areas of specialty/work**Street address**

Department of Clinical Pharmacy, School of Pharmacy, Tehran University of Medical Sciences, Tehran, Iran

City

Tehran

Postal code

1417614411

Phone

+98 21 6695 4709

Fax

+98 21 6695 4709

Email

anqarekhani@yahoo.com; gharekhani@razi.tums.ac.ir

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*