

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the effect of nutrition based education program with two grams omega 3 daily on fatigue in hemodialysis patients compared to non-receipt of such interventions as control group

Protocol summary

Summary

The study population included all hemodialysis patients in the Military hospital and the study population consist of 66 hemodialysis patients hospitalized in Imam Reza hospital , and Hagar hospital and bessat hospital. Specific goals include: to determine the fatigue of education and omega-3 and control groups before intervention and To determine the fatigue of education and omega-3 and control groups after the intervention and To determine the fatigue of education and omega-3 and control groups before and after intervention. Three study groups (intervention group 1: receiver-based nutrition education and intervention group 2: receiving the omega-3 and the control group) randomly between Hajar hospital, Imam Reza hospital and Bessat hospital were selected. Patients with at least six months of dialysis, dialysis three times a week and have no history of infectious disease and cancer are selected. It should be explained to the patient and their written informed consent is obtained. Patients are asked to complete a questionnaire the MFI. After completing the questionnaire, the control group receiving conventional care and test a "training in two sessions on a two-hour lecture and instructional booklet and pamphlet and a meeting of bug fixes as questions and answers received. Groups 2: 2 grams of omega-3 capsules daily for 8 weeks out. After eight weeks, all three groups again complete by the beginning of the MFI questionnaire. At the end, the data with statistical analysis will be done by SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091020041N3**
Registration date: **2016-01-13, 1394/10/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-01-13, 1394/10/23

Registrant information

Name

Armin Zareiyan

Name of organization / entity

Military University of Medical Science (AJA)

Country

Iran (Islamic Republic of)

Phone

+98 21 7765 4000

Email address

a.zareian@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Military University of Medical Science Vice Chancellor for Research.

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2015-12-06, 1394/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of nutrition based education program with two grams omega 3 daily on fatigue in

hemodialysis patients compared to non-receipt of such interventions as control group

Public title

Comparison of nutrition based education program and Omega-3 Supplements on Fatigue in hemodialysis patient

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients willing to participate in the study, be able to read and write, at least 6 months have passed since their dialysis, 3 times a week dialysis, no history of malignant disease and inflammatory disease and infection, no history of kidney transplants, lack of immunosuppressive and Anti-depressant drugs, lack of a ban on the consumption of omega-3 supplement, not allergic to seafood and omega-3, the Permissions from the head of dialysis (nephrologist) for using omega 3. Exclusion criteria: An unwillingness to cooperate each of the samples, the risk of malignant and inflammatory diseases during the study, the appearance of any allergies or reactions to omega-3.

Age

From **20 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In order to randomly select two intervention (group I) and control groups (group III), Toss and coin method was used for selecting one of Hajar, Imam Reza and Bessat hospital. Intervention group1 (intervention: get the nutrition Based education program): Imam Reza Hospital Intervention group2 (intervention: two grams daily of omega-3 capsules): Hajar hospital The control group (no intervention is done): Bessat Hospital Samples of each group are selected from the respective hospital dialysis unit.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Military University of Medical Science.

Street address

Etemadzade Ave., Fatemi Crossroad

City

Tehran

Postal code

1411718541

Approval date

2015-01-14, 1393/10/24

Ethics committee reference number

9323

Health conditions studied

1

Description of health condition studied

Fatigue

ICD-10 code

F48

ICD-10 code description

Neurasthenia

2

Description of health condition studied

Hemodialysis

ICD-10 code

Z49.1

ICD-10 code description

Extracorporeal dialysis

Primary outcomes

1

Description

Fatigue

Timepoint

Before and eight weeks after intervention

Method of measurement

Multidimensional Fatigue Inventory_20

Secondary outcomes

empty

Intervention groups

1

Description

Based nutrition education: providing training in two-hour in two group training sessions to lecture and provide content and training manuals and pamphlets and a question and answer session to be bug fixes.

Category

Behavior

2

Description

Two grams of omega 3 capsules daily for eight weeks taking orally

Category

Treatment - Drugs

3

Description

there is no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hajar Hospital

Full name of responsible person

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Street address

City

Tehran

3

Recruitment center

Name of recruitment center

Bessat Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Military University of Medical Science Vice Chancellor for Research.

Full name of responsible person

Kamran Azma

Street address

Etemadzade Ave., Fatemi Crossroad

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Military University of Medical Science Vice Chancellor for Research.

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

Military University of Medical Science

Full name of responsible person

Mohammad Tavakoli

Position

Critical Care Nursing Graduate Student

Other areas of specialty/work

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Contact

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Full name of responsible person

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Position

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Other areas of specialty/work

Street address

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Phone

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