Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Sep 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

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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
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Mohammad Tavakoli
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Person responsible for updating data

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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