

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Evaluation of the effect of omega-3 supplementation on serum lipid in patients with chronic dialysis

#### Protocol summary

##### Summary

Evaluation of the effect of omega-3 supplementation on serum lipid in patients with chronic dialysis Objectives: This study has been done to examine the complementary effects of omega lipid on High Density Lipoprotein (HDL), Low Density Lipoprotein (LDL), Triglyceride (TG) and Cross reacting Protein (CRP) profile serums In Patients with chronic hemodialysis. Design: This clinical trial will be done randomly and double blind with using placebo. They will be chosen from among the patients called on hemodialysis unit of Ardabil BUALI Hospital. Setting and Conduct: Patients will be grouped in two intervention and control groups. Intervention group will receive one omega 3 Capsule and control group will receive one placebo capsule for three months. Study indexes will be measured before and after intervention in laboratory. Major Inclusion and Exclusion Criteria: This intervention will include patients with following conditions: 1. Patients that have been received dialysis therapy for more than three months. 2. Patients that have been received no anti-lipid drugs as yet. Patients that can't tolerate drugs receive or not interested in drugs receive or die during intervention will exclude from intervention. Intervention: In used intervention we will prescribe omega Max Capsule to 30 patients of intervention group and placebo capsule to 30 patients of control group. We will do intervention from 06.12.2014 until 20.03.2015. Main outcome measures variables: Main outcome measures variables are TG, HDL and LDL that will be studied before and after of interval.

#### General information

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT2014112520087N1**

Registration date: **2015-05-24, 1394/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-05-24, 1394/03/03

##### Registrant information

###### Name

Elnaz Khodaei Ardabili

###### Name of organization / entity

Ardabil University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 45 3352 9580

###### Email address

elnaz.khodaei@arums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research, Ardabil University Of Medical Sciences

##### Expected recruitment start date

2014-12-06, 1393/09/15

##### Expected recruitment end date

2015-03-20, 1393/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of omega-3 supplementation on serum lipid in patients with chronic dialysis

##### Public title

Examine the complementary effects of omega lipid on lipid profile serum and compare it with effect of placebo of omega in patients With Chronic dialysis.

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Patients that have been receive dialysis therapy for more than three months: patients that have been received no anti-lipid drugs as yet. Exclusion criteria for the study: Patients that can't tolerate drugs receive: patients not interested in drugs receive: patients die during intervention.

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Patients of omega and placebo groups will be selected randomly. Omega group patients will select among patients dialysis on Saturday, Monday and Wednesday and placebo group patients will select among patients dialysis on Sunday, Tuesday and Thursday.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ardabil University Of Medical Sciences

##### Street address

Ardabil University Of Medical Sciences, Daneshgah Street.

##### City

Ardabil

##### Postal code

56198-53141

#### Approval date

2014-07-27, 1393/05/05

#### Ethics committee reference number

93.48.Arums.REC

## Health conditions studied

### 1

#### Description of health condition studied

End stage renal disease

#### ICD-10 code

N18

#### ICD-10 code description

Chronic kidney disease

## Primary outcomes

### 1

#### Description

High Density Lipoprotein (HDL)

#### Timepoint

Before and three months after intervention

#### Method of measurement

Laboratory measurement of serum HDL concentrations in scale mili mol / lit

### 2

#### Description

Low Density Lipoprotein (IDL)

#### Timepoint

Before and three months after intervention

#### Method of measurement

Laboratory measurement of serum LDL concentrations in scale mili mol / lit

### 3

#### Description

Triglyceride(TG)

#### Timepoint

Before and three months after intervention

#### Method of measurement

Laboratory measurement of serum TG concentrations in scale mili mol / lit

## Secondary outcomes

### 1

#### Description

Cross Reacting Protein (CRP)

#### Timepoint

Before intervention, three months after intervention

#### Method of measurement

Laboratory measurement of serum CRP concentrations in scale Mg / dl

## Intervention groups

### 1

#### Description

Control: Daily one placebo of Omega Max made in Zahravi Pharmaceutical Company for three months Prescribed.

#### Category

Placebo

## 2

### Description

Intervention group: Daily one Omega Max Capsule made in Zahravi Pharmaceutical Company containing 400 mg Eicosapentanoic Acid and 300 mg Decosa Hexanoic Acid for three months prescribed.

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hemodialysis Unit, Ardabil Buali Hospital.

##### Full name of responsible person

Hemodialysis Unit supervisor, MA.Nursing, Rita Shamshiri

##### Street address

Hemodialysis Unit, Ardabil Buali Hospital, Moallem Street.

##### City

Ardabil

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice Chancellor for research of Ardabil University of Medical Sciences

##### Full name of responsible person

Dr. Shahram Habibzadeh

##### Street address

Vice Chancellor for research of Ardabil University of Medical Sciences, kowsar town

##### City

Ardabil

##### Grant name

-

##### Grant code / Reference number

-

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

Yes

##### Title of funding source

Vice Chancellor for research of Ardabil University of Medical Sciences

##### 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

Ardabil University of Medical Sciences

#### Full name of responsible person

Dr. Bahman Bashardoost

#### Position

Nephrologist, faculty members of medical sciences

#### Other areas of specialty/work

#### Street address

Ardabil Emam Khomeini Hospital, Shahid Jeddi Street.

#### City

Ardabil

#### Postal code

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#### Phone

+98 45332514018

#### Fax

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#### Email

bahman.bashardoost@arums.ac.ir

#### Web page address

-

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Ardabil university of medical sciences

#### Full name of responsible person

Dr. Bahman Bashardoost

#### Position

Nephrologist

#### Other areas of specialty/work

#### Street address

Ardabil Emam Khomeini Hospital - Shahid jeddi Street.

#### City

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#### Postal code

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#### Phone

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#### Fax

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#### Email

bahman.bashardoost@arums.ac.ir

#### Web page address

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## Person responsible for updating data

### Contact

#### Name of organization / entity

Ardabil University Of Medical Sciences

#### Full name of responsible person

Dr. Elnaz Khodaei Ardabili

**Position**

Internal medicine assistant

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

Ardabil Emam Khomeini Hospital - Shahid jeddi  
Street.

**City**

Ardabil

**Postal code**

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**Phone**

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**Fax**

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**Email**

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**Web page address**

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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*