

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of omega-3 fatty acid supplementation on endothelial function in end-stage renal disease: a randomized controlled trial

Protocol summary

Study aim

Evaluating the effect of Omega-3 supplementation on endothelial function in patients with end-stage renal disease.

Design

Randomized, superiority, parallel-group trial with blinded outcome assessment. Randomization was centralized and computerized with concealed randomization sequence carried out at an external site

Settings and conduct

This study will be conducted in the hemodialysis ward of a university-affiliated tertiary care center. After recruiting the patients based on the inclusion and exclusion criteria, the baseline numerical value of flow-mediated vasodilation will be measured in all these patients (by an experienced sonographer). Patients will be randomly allocated into two groups. One group will receive omega-3 supplements and the second group will receive a placebo (double-blind). Following the treatment period, the measurement of flow-mediated vasodilation will be repeated for both groups. The difference observed in the flow-mediated vasodilation variable between the two groups will be assessed and compared.

Participants/Inclusion and exclusion criteria

Known cases of end-stage renal disease (ESRD) will be included in the study. Patients under 18, patients with active infection, patients with severe heart failure, and patients in whom the vascular anatomy of the cubital area is bilaterally injured will be excluded.

Intervention groups

One group of patients will receive Omega-3 supplementation, and the second group will receive a placebo.

Main outcome variables

The numerical value of the flow-mediated vasodilation which is calculated using the sonography machine based on percentage. This will be a continuous variable.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220611055142N1**

Registration date: **2022-07-07, 1401/04/16**

Registration timing: **prospective**

Last update: **2022-07-07, 1401/04/16**

Update count: **0**

Registration date

2022-07-07, 1401/04/16

Registrant information

Name

اخوی میلانی آلی

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3442 8855

Email address

ali.akhavi.milani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of omega-3 fatty acid supplementation on endothelial function in end-stage renal disease: a randomized controlled trial

Public title
Omega-3 on vascular function in hemodialysis patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with End-stage renal disease undergoing regular hemodialysis
Exclusion criteria:
 Age group under 18 Diagnosed with active infection
 Diagnosed with severe heart failure Bilaterally Injured cubital vascular anatomy

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, a simple randomization method will be used. Patients (36 patients) will be numbered based on the date of their visit. Subsequently, 36 numbers will be written on 36 cards from 1 to 36 and then 18 cards will be randomly selected and these numbers will be placed in the intervention group and will receive omega-3. The remainder of the patients will be placed in the control group and will receive a placebo.

Blinding (investigator's opinion)
Double blinded

Blinding description
Neither the patients nor the caregiver who will give the medicines to the patients will be unaware of the type of the medicines. The sonographer who will calculate the vascular diameters will also be unaware.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Tabriz university of medical sciences

Street address

Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5177658847

Approval date

2022-04-06, 1401/01/17

Ethics committee reference number

IR.TBZMED.REC.1401.056

Health conditions studied

1

Description of health condition studied

End stage renal disease (ESRD)

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

The numerical value of flow-mediated vasodilation which is calculated using sonography machine based on percentage.

Timepoint

Calculation of flow-mediated vasodilation, once in the beginning of the study (baseline values before initiation of the treatment), and subsequently, three weeks following the continuation of Omega-3 supplementation.

Method of measurement

The numerical number will be calculated using sonography machine.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pearl Omega-3 1000 mg (Zahravi Pharmaceutical Company) daily for 3 weeks will be prescribed to the patients in the intervention group. The usage method will be elucidated to the patient upon administration and the usage correctness will be assured on each visit of the patients to the hemodialysis ward

(these patients usually visit the hemodialysis ward three days a week).

Category

Treatment - Drugs

2**Description**

Control group: Placebo pearls with identical physical appearance manufactured by the same pharmaceutical company (Zahravi) will be prescribed to be taken daily for three weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Reza Hospital

Full name of responsible person

Ali Akhavi Milani

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Parviz Shahabi

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries**Contact****Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Ali Akhavi Milani

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

Professor

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Subspecialist

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All the potential data acquired from the patients after de-identification

When the data will become available and for how long

Available just following the publication.

To whom data/document is available

None.

Under which criteria data/document could be used

Every request sent through the editorial board of the publishing journal.

From where data/document is obtainable

The e-mail of the corresponding author:
ali.akhavi.milani@gmail.com

What processes are involved for a request to access data/document

The requests submitted to the corresponding author's e-mail will be answered within seven days.

Comments