

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### Evaluation and Comparison of the Effectiveness of Herbal Omega3 Supplements (flax seed) and Animal Based Omega3 on Fetuin Level in Patient with Chronic Kidney Disease

#### Protocol summary

##### Study aim

Determination and comparison of the effect of omega-3 supplements of plant (flax seed) and animal origin on the level of fetuin in patients with chronic renal failure

##### Design

Clinical trials with control group, With parallel groups, Double blind, Randomized

##### Settings and conduct

Patients are randomly divided into 3 groups of 30. The first daily dose is 2 tablets of 1 g of omega-3, and the second group receives 2 tablets of 1 g of omega-3 herb (flax seed) and the third group receives a placebo. The study period is 90 days. In each of the three groups, before and after the study, Blood fetuin, CRP, ESR, TG, HDL, LDL are measured and compared by blood sampling. Researcher, patients, and drug-related tests are not known.

##### Participants/Inclusion and exclusion criteria

1. The patient above 18 years  
2. Glomerular Filtration Rate between 15 to 60  
1. Allergen to omega3 products  
2. Infection and inflammation disease

##### Intervention groups

The follow up of the groups is as below: The first group by daily intake of two 1 g omega 3 tablets with animal origin (fish oil), The second group by daily intake of two 1 g omega 3 tablets with plant origin (flax seed oil), And the third group as control group without intake of omega 3.

##### Main outcome variables

Fetuin-A; High-density lipoprotein; Low-density lipoprotein; Erythrocyte sedimentation rate; C-reactive protein; Triglyceride

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180820040839N1**

Registration date: **2019-03-02, 1397/12/11**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-03-02, 1397/12/11**

Update count: **0**

#### Registration date

2019-03-02, 1397/12/11

#### Registrant information

##### Name

Elham Khodadustan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 38 3334 5742

##### Email address

st-khodadustan.e@skums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-12-16, 1397/09/25

#### Expected recruitment end date

2019-03-16, 1397/12/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation and Comparison of the Effectiveness of Herbal Omega3 Supplements (flax seed) and Animal Based

Omega3 on Fetuin Level in Patient with Chronic Kidney Disease

## Public title

Effect of omega3 on fetuin level

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

The patient above 18 years Glomerular Filtration Rate between 15 to 60

### Exclusion criteria:

Allergen to omega3 products Infection and inflammation disease

## Age

From 18 years old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: 90

## Randomization (investigator's opinion)

Randomized

## Randomization description

Individuals are divided into three groups by simple randomization with random numbers table and receive the intervention related to the same group.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients from 1 to 90 divided randomly into three groups that every group have 30 members, then without conscience of patients, head of laboratory and data analyzer, data collection done

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahrekord Medical University

##### Street address

Shahrekord, Nursing Street, Hajar Hospital

##### City

shahrekord

##### Province

Chahar-Mahal-va-Bakhtiari

## Postal code

8816754633

## Approval date

2017-07-19, 1396/04/28

## Ethics committee reference number

IR.SKUMS.REC.1396.94

## Health conditions studied

### 1

#### Description of health condition studied

chronic kidney disease

#### ICD-10 code

N18.3

#### ICD-10 code description

Chronic kidney disease, stage 3 (moderate)

### 2

#### Description of health condition studied

chronic kidney disease

#### ICD-10 code

N18.4

#### ICD-10 code description

Chronic kidney disease, stage 4 (severe)

## Primary outcomes

### 1

#### Description

measurement of serum fetuin

#### Timepoint

Measurement of serum fetuin in the beginning of the study (before the intervention) and 90 days after medication

#### Method of measurement

fetuin kit in laboratory

## Secondary outcomes

### 1

#### Description

measurement of serum HDL

#### Timepoint

Measurement of serum HDL levels early in the study (before the start of the intervention) and 90 days after starting the medication

#### Method of measurement

HDL kit in laboratory

### 2

#### Description

measurement of serum LDL

#### Timepoint

Measurement of serum LDL levels early in the study (before the start of the intervention) and 90 days after starting the medication

**Method of measurement**

LDL kit in laboratory

**3****Description**

measurement of serum TG

**Timepoint**

Measurement of serum TG levels early in the study (before the start of the intervention) and 90 days after starting the medication

**Method of measurement**

TG kit in laboratory

**4****Description**

measurement of serum ESR

**Timepoint**

Measurement of serum ESR levels early in the study (before the start of the intervention) and 90 days after starting the medication

**Method of measurement**

ESR kit in laboratory

**5****Description**

measurement of serum CRP

**Timepoint**

Measurement of serum CRP levels early in the study (before the start of the intervention) and 90 days after starting the medication

**Method of measurement**

CRP kit in laboratory

**Intervention groups****1****Description**

Intervention group: The first group are 30 people who receive 2 tablet of 1 gram animal's omega3(fish oil) per day for 90 days from the Zakhraavi factory in Tabriz .

**Category**

Treatment - Drugs

**2****Description**

Intervention group: The second group are 30 people who receive 2 tablet of 1 gram of herbal's omega 3(flaxseed) per day for 90 days from Kashan Barij Company .

**Category**

Treatment - Drugs

**3****Description**

Control group: The third group are 30 people who receive 1 placebo tablet per day for 90 days from kashan Barij Company.

**Category**

Treatment - Drugs

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

Hajar Hospital

**Full name of responsible person**

Elham Khodadustan

**Street address**

Hajar Hospital, Nursing Street

**City**

Shahre-kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8816754633

**Phone**

+98 38 3222 0016

**Email**

e.khodadustan@gmail.com

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

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Dr. Seyed Kamal Solati

**Street address**

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

**City**

Shahre-kord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8816754633

**Phone**

+98 38 3333 8891

**Email**

e.khodadustan@gmail.com

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

Yes

**Title of funding source**

Shahre-kord 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

8816754633

**Phone**

+98 38 3222 0016

**Email**

mahmoodnia.l@skums.ac.ir

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

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Elham Khodadustan

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

Parastar Street, Hajar Hospital

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8816754633

**Phone**

+98 38 3222 0016

**Email**

e.khodadustan@gmail.com

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

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Elham Khodadustan

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

**Street address**

Hajar hospital, Parastar Street

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

**Postal code**

8816754633

**Phone**

+98 38 3222 0016

**Email**

e.khodadustan@gmail.com

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

Shahre-kord University of Medical Sciences

**Full name of responsible person**

Leila Mahmoodnia

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Hajar hospital, Parastar Street

**City**

Shahrekord

**Province**

Chahar-Mahal-va-Bakhtiari

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

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Dissatisfaction patients

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available