Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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.Gleumerolar Filtration Rate between15 to 60 1.Allergen to omega3 products 2.Infection and inflamation disease

Intervention groups
The follow up of the groups is as bellow: 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 Gleumerolar Filtration Rate between15 to 60
Exclusion criteria:
Allergen to omega3 products Infection and inflamation 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 randomally into three groups that every group have 30 members, then without conscience of patients, head of laboratory and data analyzer, data collection dose
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
mesurement of serum fetoin
Timepoint
Measurement of serum fetoin in the beginning of the study (before the intervention) and 90 days after medication
Method of measurement
fetoin kit in laboratory

Secondary outcomes

1

Description
measurement of seum 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 seum 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 seum 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 seum 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 seum 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 Zakhravi 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 omeg 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
Shahrekord
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
Shahrekord
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

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 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
8816754633
Phone
+98 38 3222 0016
Email
mahmoodnia.l@skums.ac.ir

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

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