Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of supplemental omega-3 and zinc supplementation on inflammation, lipid profiles and antioxidant capacity in type 2 diabetic patients

Protocol summary

Study aim
The aim of this study is evaluate the effect of omega-3 and zinc supplements on inflammatory status, lipid profiles and antioxidant capacity in type 2 diabetic patients.

Design
In this study, 80 patients with type 2 diabetes who were admitted to study at the endocrine clinic of Imam Khomeini Hospital in Urmia were selected. The participants are randomly divided into four intervention and control groups and each participant is assigned a code.

Settings and conduct
This study will be conducted at Urmia University of Medical Sciences for 8 weeks. In this study, 1000 mg of omega-3 (180 mg of eicosapentaenoic acid and 120 mg of deca-hexaenoic acid) and 30 mg of zinc per day will be given.

Participants/Inclusion and exclusion criteria
Inclusion criteria include people with type 2 diabetes without insulin injections. Insulin infusion and kidney problems are among the criteria for withdrawal.

Intervention groups
Patients were randomly will be divided into 3 intervention groups including interventional group with omega-3 (n = 20), interventional group with Zn (n = 20), interventional group omega-3 with zinc (n = 20) and placebo group (n = 20).

Main outcome variables
Lipid profile (total cholesterol; HDL; LDL; triglyceride); inflammatory status (Hs-CRP); total antioxidant capacity (TAC) in this study once at the beginning of the study and once at the end of the study will be evaluated.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170214032571N2**
Registration date: **2018-01-13, 1396/10/23**
Registration timing: **retrospective**

Last update: **2018-03-11, 1396/12/20**
Update count: **1**

Registration date
2018-01-13, 1396/10/23

Registrant information
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Recruitment status
Recruitment complete

Funding source
Support by Urmia University of Medical Sciences

Expected recruitment start date
2016-09-30, 1395/07/09

Expected recruitment end date
2016-11-20, 1395/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of supplemental omega-3 and zinc supplementation on inflammation, lipid profiles and antioxidant capacity in type 2 diabetic patients

Public title
The effect of omega-3 and zinc in the treatment of diabetes

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
tendency to Cooperation Type 2 diabetic patients ; taking metformin or glibenclamide glucose or similar drugs by patients Age range 18 to 65 years use of lipid lowering statin drugs and a blood pressure lowering drugs

Exclusion criteria:
Unwillingness to participate in the study Insulin injection Do not consume 80% of supplements per course People with pancreatic cancer and patients receiving steroidal anti-inflammatory drugs (due to secondary hyperglycemia) severe physical activity Use of omega-3 and zinc supplementation in the last three months developing any underlying coronary artery disease and cancer taking antidepressants (because of interactions with zinc supplementation)

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were divided into 4 equal groups of 20 (A total of 80),A , B, C and D, by using simple randomization method.The study groups included omega-3 (A), zinc (B), omega-3 and zinc (C), and placebo-control group (D).Randomization was assigned to a random assignment list by a research team member.

Blinding (investigator's opinion)
Double blinded

Blinding description
Randomization was assigned to a random assignment list by a research team member as the only non-blind person. Other members of the research team (including team leader and study coordinator) as well as all participants participated in the random allocation of blind groups and remained blind until the end of the study.In fact, in this study, patients were blinded to use of placebo or supplementation. Also, all of the study subjects were blind except for one group.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics Committee of Urmia University of Medical Sciences

Street address
Nutrition Department, Faculty of Medicine, College of Medicine, Urmia University of Medical Science, 11th km of Nazloo Road, Urmia

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Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2016-09-09, 1395/06/19

Ethics committee reference number
IR.UMSU.REC.1395.370

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E10, E11,

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Total cholesterol

Timepoint
Before intervention and two months after intervention

Method of measurement
Enzymatic method, mg / dl

2

Description
TAC

Timepoint
Before intervention and two months after intervention

Method of measurement
Colorimetric

3

Description
hs-crp
Timepoint
Before intervention and two months after intervention
Method of measurement
Eliza-mg/dl

4

Description
HDL
Timepoint
Before intervention and two months after intervention
Method of measurement
Enzymatic method, mg / dl

5

Description
Tri glyceride
Timepoint
Before intervention and two months after intervention
Method of measurement
Enzymatic method, mg / dl

6

Description
LDL
Timepoint
Before intervention and two months after intervention
Method of measurement
Enzymatic method, mg / dl

Secondary outcomes

empty

Intervention groups

1

Description
Group A = Intervention group with omega-3 doses of 1000 mg with lunch
Category
Treatment - Drugs

2

Description
Group C = Omega 3 group with zinc
Category
Treatment - Drugs

3

Description
Group A = Intervention group with zinc dose of 30 mg in the evening meal
Category
Treatment - Drugs

4

Description
Group D = Receptor of Starch Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital of Urmia
Full name of responsible person
Dr. Peyvand Mohammadi Endocrinologist
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Sponsors / Funding sources

1

Sponsor
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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
Urmia 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
Urmia University of Medical Sciences
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Master of Science in Nutrition Sciences
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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
Unwillingness to publish individual data
Study Protocol
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
In this study, only the original outcome can be published

When the data will become available and for how long

Start the access period one year after the print results

To whom data/document is available

People working in academic institutions

Under which criteria data/document could be used

is not allowed type of analysis on data

From where data/document is obtainable

Phone number 09132801511 and email mehdikhakian1371@yahoo.com

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

Applicants will be able to access data after two months of requesting data, with full details of their profile.

Comments