

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

Name

Majid Manafi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 32770698

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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

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

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Urmia

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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

Street address

Floor 2, Imam Khomeini Hospital professional clinic (1), Ershad Ave urmia West Azarbgijan

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Urmia University of Medical Sciences

Full name of responsible person

Mehdikhakian

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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

Full name of responsible person

Majid Monafi

Position

Master of Science in Nutrition Sciences

Latest degree

Master

Other areas of specialty/work

Nutrition

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Full name of responsible person

Majid Manafi

Position

Masters of Nutrition

Latest degree

Master

Other areas of specialty/work

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Full name of responsible person

Majid Monafi

Position

Masters

Latest degree

Master

Other areas of specialty/work

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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