

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effect of supplementation of omega-3 and zinc on liver and kidney parameters in type 2 diabetic patients

Protocol summary

Study aim

The effect of omega-3 and zinc supplements on liver and kidney parameters in type 2 diabetic patients

Design

This study was performed as a randomized, parallel controlled clinical trial on 80 patients with type 2 diabetes.

Settings and conduct

This study was performed as a randomized, parallel controlled clinical trial on 80 patients with type 2 diabetes. In this study, while receiving written informed consent from patients, participants were blinded to receiving drugs and placebo.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: type 2 diabetes and age range older than 18 years Non-inclusion criteria: insulin infusion. kidney disease. Severe physical activity during the intervention

Intervention groups

Patients were divided into three groups of intervention and one control group. The intervention group with Omega-3, The intervention group with Zinc, the intervention group with omega-3 and zinc and placebo group

Main outcome variables

Indicators of liver (ALT, AST, ALP, GGT and albumin) and renal indices (creatinine, uric acid and blood urea)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180201038585N1**

Registration date: **2018-03-10, 1396/12/19**

Registration timing: **retrospective**

Last update: **2018-03-10, 1396/12/19**

Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Karim Parastouei

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8248 3516

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parastouei@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

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 supplementation of omega-3 and zinc on liver and kidney parameters in type 2 diabetic patients

Public title

The effect of supplementation of omega-3 and zinc on the treatment of type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adults with Type 2 Diabetes

Exclusion criteria:

Insulin injection Pregnancy and lactation Pancreatic cancer

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 groups 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).

Blinding (investigator's opinion)

Double blinded

Blinding description

Intervention and randomization through a random allocation list was made by a member of the research team as the only non-blind person to be assigned. Other team members (including team leader and study coordinator), as well as all participants, were randomly allocated to blind groups and remained blind until the end of the study.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethics Committee of the University of Medical Sciences

Street address

Mollasadra street, Vanak Square, Baqiyatallah University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2017-05-02, 1396/02/12

Ethics committee reference number

IR.BMSU.REC.1396.6992

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

Alanine aminotransferase

Timepoint

At weeks 0, 8

Method of measurement

Enzymatic method-IU/Lit

2**Description**

Aspartate aminotransferase

Timepoint

At weeks 0, 8

Method of measurement

Enzymatic method-IU/Lit

3**Description**

Gamma glutamyl transpeptidase

Timepoint

At weeks 0, 8

Method of measurement

Enzymatic method-IU/Lit

4**Description**

Alkaline phosphatase

Timepoint

At weeks 0, 8

Method of measurement

Enzymatic method-IU/Lit

5**Description**

Creatinine

Timepoint

At weeks 0, 8

Method of measurement

Enzymatic method, mg/dl

6

Description

Uric acid

Timepoint

At weeks 0, 8

Method of measurement

Enzymatic method, mg/dl

7

Description

Urea

Timepoint

At weeks 0, 8

Method of measurement

Enzymatic method, mg/dl

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Group A = Intervention with omega-3 at a dose of 1000 mg daily one number capsule for 8 weeks - Dana Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Intervention group: Group B: Intervention with zinc at a dose of 30 mg daily One number tablet for 8 weeks - Dine Pharmaceutical Company

Category

Treatment - Drugs

3

Description

Intervention group: Group C: Intervention with omega-3 at a dose of 1000 mg plus zinc at a dose of 30 mg daily for 8 weeks

Category

Treatment - Drugs

4

Description

Control group: Group D: In this study, individuals in the control group received one capsule 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

Street address

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

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mehdikhakian1371@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Karim Parastouei

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Baqiyatallah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Karim Parastouei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available