

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Evaluating the effect of omega-3 and zinc oral supplementation on glycemic index, serum zinc levels, body composition and blood pressure in type 2 diabetic patients

Protocol summary

Study aim

Evaluating the effect of omega-3 and zinc oral supplementation on glycemic index, serum zinc levels, body composition and blood pressure in type 2 diabetic patients

Design

This study will be conducted as a randomized, parallel controlled clinical trial on 80 patients with type 2 diabetes.

Settings and conduct

This study will be performed as a randomized, parallel controlled clinical trial among patients with type 2 diabetes for 8 weeks.

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 randomly divided into 3 intervention groups including omega-3 (n = 20), zinc (n = 20), omega-3 and zinc (n = 20) and placebo groups (n = 20) with intervention group (n = 20)

Main outcome variables

Glycemic indexes, serum zinc level, body composition and blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170214032571N9**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **retrospective**

Last update: **2018-02-19, 1396/11/30**

Update count: **1**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

Majid Manafi

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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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

Evaluating the effect of omega-3 and zinc oral supplementation on glycemic index, serum zinc levels, body composition and blood pressure 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:

Age range over 18 years old in both sexes Type 2 diabetes

Exclusion criteria:

Insulin injection Pregnancy and lactation Pancreatic cancer Severe physical activity during the intervention

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) 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

Assignment to study group was done by a research team member, as the only non-blind person in our study. Other team members (including team leader and study coordinator), as well as all participants remained unaware of the allocations until the end of the study.

Placebo

Used

Assignment

Parallel

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

Urmia University of Medical Sciences, orjans valley, Rresalat boulevard

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Urmia

Province

West Azarbaijan

Postal code

5715799313

Approval date

2016-09-10, 1395/06/20

Ethics committee reference number

Ir.Umsu.Rec.1395.371

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

Weight

Timepoint

At weeks 0, 8

Method of measurement

Scale, Kg

2

Description

Body mass index

Timepoint

At weeks 0, 8

Method of measurement

Weight(kg) / Height(m)²

3

Description

Insulin resistance

Timepoint

At weeks 0, 8

Method of measurement

(fasting serum glucose (mmol/L) × fasting serum insulin (μIU/ml))/22.5

4

Description

Fasting Blood Sugar

Timepoint

At weeks 0, 8

Method of measurement

Enzymatic method, mg/dl

5

Description

Quantitative Insulin Sensitivity Check Index

Timepoint

At weeks 0, 8

Method of measurement

$1 / [\log(\text{fasting insulin, } \mu\text{U/ml}) + \log(\text{fasting glucose, mg/dl})]$

6**Description**

Serum insulin

Timepoint

At weeks 0, 8

Method of measurement

Radioimmunoassay

7**Description**

Serum zinc

Timepoint

At weeks 0, 8

Method of measurement

Colorimetric

8**Description**

Systolic blood pressure

Timepoint

At weeks 0, 8

Method of measurement

Mercury pressure gauge, Mm mercury

9**Description**

Diastolic blood pressure

Timepoint

At weeks 0, 8

Method of measurement

Mercury pressure gauge, Mm mercury

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: 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: 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**

Receive one daily capsule of placebo containing starch

Category

Placebo

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

Imam Khomeini Hospital of Urmia

Full name of responsible person

Dr. Peyvand Mohammadi

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

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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Iraj Mohebi

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Orjhans street, Resalat Blvd, Urmia

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Majid Monafi

Position

Master of Science in Nutritional Science/ Faculty Member

Latest degree

Master

Other areas of specialty/work

Nutrition

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

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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