

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of omega-3 supplementation on endothelial function, vascular structure and metabolic parameters in adolescents with type 1 diabetes

Protocol summary

Study aim

Determining the effect of omega-3 supplementation on endothelial function, vascular structure and metabolic parameters in children and adolescents with type 1 diabetes

Design

The present study is a double-blind randomized, placebo-controlled randomized clinical trial in which one group received omega-3 supplements and one group received placebo. The statistical population of this study is all adolescents (10 to 18 years old), who have been diagnosed with type 1 diabetes by a specialist.

Settings and conduct

Participants are selected from Mofid Children's Hospital according to the inclusion and exclusion criteria of a study

Participants/Inclusion and exclusion criteria

Inclusion criteria Adolescents 10 to 18 years Body mass index of people between 5 to 85 percent Type 1 diabetes according to the doctor's diagnosis and receiving insulin routine At least 5 years have passed since the diagnosis of type 1 diabetes Willingness to cooperate Exclusion criteria Consumption of antihypertensive and lipid lowering drugs, anticoagulants or anti-inflammatory drugs and weight loss substances and drugs, history of using anti-inflammatory and antioxidant supplements and omega 3 in the last 6 months, endocrine and metabolic diseases history of fish and seafood allergies Acute disease that needs treatment smoking Systolic or diastolic blood pressure above 90 percent Pregnancy and lactation Diabetic ketoacidosis in the last 12 months or hypoglycemia (blood sugar less than 50 mg / dl) in the last 3 months

Intervention groups

Patients take a daily 600 mg supplement containing 120 mg DHA and 180 mg EPA or placebo for 12 weeks. Its omega 3 placebo is designed by Karen Pharmaceutical Company (Yazd, Iran) in appearance and color similar to omega 3 capsules (containing 600 mg of oral glycerin).

Main outcome variables

flow mediated dilation; CIMT; Lipid profile; FBS; Blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210419051010N1**

Registration date: **2021-04-29, 1400/02/09**

Registration timing: **prospective**

Last update: **2021-04-29, 1400/02/09**

Update count: **0**

Registration date

2021-04-29, 1400/02/09

Registrant information

Name

Masoud Khorshidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4402 6460

Email address

khoshshidi.2065@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-20, 1400/02/30

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of omega-3 supplementation on endothelial function, vascular structure and metabolic parameters in adolescents with type 1 diabetes

Public title
The effect of omega-3 supplementation on endothelial function, vascular structure and metabolic parameters in adolescents with type 1 diabetes

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Adolescents 10 to 18 years Body mass index of people between 5 and 85 percent Having type 1 diabetes as determined by doctor and receiving insulin routine At least 5 years have passed since the diagnosis of type 1 diabetes Willingness to cooperate
Exclusion criteria:

Age
From **10 years** old to **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
For randomization, the size 4 random blocks method is used, produced by Excel software and the process of placing patients in groups is determined based on these blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study is a two-way blind study in which participants, researchers, observers and analysts are not aware of the contents of the cans. In order to hide, a unique code is inserted by the manufacturer on the cans containing omega 3 and placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Shahid Hemmat Highway Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-04-20, 1400/01/31

Ethics committee reference number

IR.IUMS.REC.1400.070

Health conditions studied

1

Description of health condition studied

Type 1 diabetes

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

flow mediated dilation

Timepoint

At the beginning of the study and 12 weeks after starting the omega-3 supplementation

Method of measurement

Doppler ultrasound device

Secondary outcomes

1

Description

Carotid intima-media thickness

Timepoint

At the beginning of the study and 12 weeks after starting the omega-3 supplement

Method of measurement

Doppler ultrasound device

2

Description

Fasting plasma glucose

Timepoint

Before and after intervention
Method of measurement
Enzyme assay

3

Description
Total cholesterol
Timepoint
Before and after intervention
Method of measurement
Photometric

4

Description
High density lipoprotein
Timepoint
Before and after intervention
Method of measurement
Photometric

5

Description
Low density lipoprotein
Timepoint
Before and after intervention
Method of measurement
Calculation

6

Description
Triglyceride
Timepoint
Before and after intervention
Method of measurement
Photometric

7

Description
Insulin
Timepoint
Before and after intervention
Method of measurement
ELISA

8

Description
Hemoglobin A1C
Timepoint
Before and after intervention
Method of measurement
Enzymatic method

9

Description
BMI for age Z-score
Timepoint
Before and after intervention

Method of measurement
Calculation

10

Description
Weight
Timepoint
Before and after intervention
Method of measurement
Scale

11

Description
Physical activity
Timepoint
Before and after intervention
Method of measurement
Questionnaire

12

Description
hs-CRP
Timepoint
Before and after intervention
Method of measurement
ELISA

13

Description
ESR
Timepoint
Before and after intervention
Method of measurement
Measurement of erythrocyte sedimentation rate with a special tube

14

Description
Diastolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Manometer

15

Description
Systolic blood pressure
Timepoint
Before and after intervention
Method of measurement
Manometer

16

Description
Creatinine
Timepoint
Before and after intervention

Method of measurement

Enzymatic method

17

Description

Blood urea nitrogen concentration

Timepoint

Before and after intervention

Method of measurement

Diacetylmonoxim

18

Description

Proteinuria

Timepoint

Before and after intervention

Method of measurement

24-hour urine measurement

19

Description

Daily insulin received

Timepoint

Before and after intervention

Method of measurement

questionnaire

20

Description

HOMA-IR

Timepoint

Before and after intervention

Method of measurement

Calculation

21

Description

QUICKI

Timepoint

Before and after intervention

Method of measurement

Calculation

Intervention groups

1

Description

Intervention group: Omega3

Category

Treatment - Drugs

2

Description

Control group: Placebo

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Masoud Khoshidi

Street address

Mofid Children's Hospital, Shariati St., Tehran, Iran

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1983963113

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info-mch@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Dr. Seyed Abbas Motavlian

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1449614535

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ivco@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Nahid Aryaeian
Position
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Latest degree
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Person responsible for updating data

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Name of organization / entity
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khorshidi.2065@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

No - There is not 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

Title and more details about the data/document

All unidentifiable data can be shared

When the data will become available and for how long

The start of the data access period is 6 months after the results are published

To whom data/document is available

All researchers, policymakers and people in the industry

Under which criteria data/document could be used

There will be no other condition

From where data/document is obtainable

Name: Masoud Khorshidi Email: khorshidi.2065@gmail.com telephone: 00982186709
Address: Faculty of Health, Iran University of Medical Sciences, Hemmat Highway, Tehran, Iran.

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

Send the request via email to the respondent, check the email within 2 weeks and reply to the email

Comments