Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effect of omega-3 supplementation on lipid profile, insulin resistance, inflammatory parameters and SIRT1 gene expression in obese children and adolescents, a randmized placebo controlled clinical trial

Protocol summary

Summary

obesity is currently one of the main clinical complains. Metabolic syndrome is a complication of obesity and is a combination of central obesity, dyslipidemia, glucose metabolism alteration, hypertension, and insulin resistance, that may begin in childhood and progress through adulthood and increases the risk of diabetes and cardiovascular diseases. Risk of obesity and its complications is higher in obese children than normal weight children. Preventing obesity and metabolic syndrome in children prevents early occurrence of diabetes and cardiovascular disease. Sirtuins are deacetylase enzymes which act using NAD and effect gene expression by deacetylation of histones. SIRT1 is one of the sirtuins that has been shown to be associated with metabolic syndrome, insulin resistance and diabetes. This enzyme has been shown to be reduced in obesity and insulin resistance and is suggested as a marker and target for metabolic disorders. Because of the protective effect of SIRT1, its reduction in obesity may be responsible for the complications of diabetes and therefore induction of its expression may be effective in prevention of obesity complications. Studies have shown that consumption of fish and food rich in omega6 and omega 3 fatty acids are protective against obesity and cardiovascular disorders. Nowadays diet is mostly does not provide enough omega 3 and 6 fatty acids. Therefore supplementation with these fatty acids can be beneficial for health. Although many investigations have been performed in this regard, there are few studies about children and adolescents. Thus the aim of this study is to investigate the effect of eicosapentanoic acid (EPA) and docosahexaenoic acid (DHA) on lipid profile, insulin resistance, inflammatory parameters and sirtuin1 gene expression in children and adolescents and comparison with placebo. Objectives: 1-comparison of SIRT1 gene expression before and after omega 3 supplementation in omega 3 and placebo groups 2- comparison of lipid profile before and after omega 3 supplementation in omega 3 and placebo groups 3- comparison of insulin resistance parameters before and after omega 3 supplementation in omega 3 and placebo groups 4- comparison of inflammatory markers before and after omega 3 supplementation in omega 3 and placebo groups Methods: 1-Partcipants are chosen based on inclusion and exclusion criteria and are clinically evaluated. Their height and weight are measured and BMI is calculated. Blood pressure is measured. 2- omega 3 supplementation is performed for intervention for the duration of 2 months and fasting blood specimen is obtained both prior to intervention and after that. 2- Plasma is separated and kept frozen until later analysis. PBMC fraction is obtained. 3- Fasting blood glucose, triglyceride, total cholesterol, LDL-C, HDL-C, hCRP, adiponectin and visfatin are measured. 4- RNA is extracted from PBMC and cDNA is synthesized. Real-time PCR is performed using SIRT1 specific primers and beta-actin primer as housekeeping gene. difference is measured by delta Ct method. 5- SPSS software is used for statistical analysis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201612014585N10**
Registration date: **2016-12-13, 1395/09/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-12-13, 1395/09/23

Registrant information

Name

Maryam Razzaghy-Azar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6694 2903

Email address

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Recruitment status

Recruitment complete

Funding source

Iran University of Medical Sciences

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-06-22, 1396/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of omega-3 supplementation on lipid profile, insulin resistance, inflammatory parameters and SIRT1 gene expression in obese children and adolescents, a randmized placebo controlled clinical trial

Public title

Evaluation of the effect of omega-3 supplementation on lipid profile, insulin resistance, inflammatory parameters and SIRT1 in obese children and adolescents, a randmized placebo controlled clinical trial

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: BMI above 95th percentile for the specific age and gender healthy and not having any disease not taking medications specially those that interfere with lipid and carbohydrate metabolism

Exclusion criteria: BMI between 85th and 95th percentile BMI lower than 5th percentile taking medications having any other disease other than obesity

Age

From **8 years** old to **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

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

Hemmat Highway

City

Tehran

Postal code

1419614535

Approval date

2010-08-01, 1389/05/10

Ethics committee reference number

IR.IUMS.REC.1395.28694

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

Primary outcomes

1

Description

Insulin resistance

Timepoint

60 days

Method of measurement

HOMA-IR index

2

Description

inflammatory markers

Timepoint

60 days

Method of measurement

ELISA

3

Description
Sirtuin 1 gene expression
Timepoint
60 days
Method of measurement
Real-time PCR

4

Description
lipid profile
Timepoint
60 days
Method of measurement
calorimetric

Secondary outcomes

1

Description
Body mass index
Timepoint
60 days
Method of measurement
weight/height*height

Intervention groups

1

Description
Omega 3 supplement 1250 mg/day containing EPA (425 mg) and DHA (325 mg); oral; once daily for two months
Category
Treatment - Drugs

2

Description
placebo; taken as tablet once a day for 2 consecutive months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
H. Aliasghar Hospital
Full name of responsible person
Dr. Mona Nourbakhsh
Street address
H. Aliasghar hospital, Vahid Dastgerdi Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Javad Mousavi
Street address
Hemmat Highway
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Tehran
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
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Dr. Mona Nourbakhsh
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty