Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of vitamin E and n_3 PUFA supplementation on insulin resistance syndrome indices in children and adolescents.

Protocol summary

Summary

This study is destined to elucidate the effects of vitamin E and n_3 PUFA supplementation on insulin resistance syndrome indices in children and adolescence. We conducted an 8 weeks, randomized, triple blind clinical trial on 90 patients with diagnosed metabolic syndrome, being between 10-18 years old in Cardiovascular Research Center of Isfahan University of Medical Sciences. They are divided into 3 groups, each containing 30 patients. One group receives vitamin E tablets (400 IU/day), another group receives Omega-3 supplementation (2gr/day) and the other one receives placebo. All groups are given similar, appropriate exercise and diet plan during study. Insulin resistance syndrome indices as well as secondary outcomes such as total cholesterol, LDL, NO, VEGF, Fasting serum insulin level, antioxidant capacity, HOMA-IR and hs-CRP will be measured before and after this 8-week period and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138708151434N1**
Registration date: **2009-10-28, 1388/08/06**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-10-28, 1388/08/06

Registrant information

Name

Roya Kelishadi

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 3060

Email address

kelishadi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2008-12-31, 1387/10/11

Expected recruitment end date

2009-12-31, 1388/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of vitamin E and n_3 PUFA supplementation on insulin resistance syndrome indices in children and adolescents.

Public title

Comparing the effect of vitamin E and Omega-3 fatty acids on metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Matching metabolic syndrome definition (based on the new definition of International Diabetes Federation (IDF) on October 2007) (The IDF consensus definition for children 10 to <16 years of age include the clustering of any three of the following risk factors: 1) obesity, waist circumference ≥ 90% based on age and gender; 2) triglycerides ≥ 150 mg/dL; 3) HDL-cholesterol < 40 mg/dL; 4) systolic blood pressure ≥ 130/

diastolic blood pressure ≥ 85 mmHg and 5) glucose ≥ 100 mg/dL. For individuals over 16 years old, the adult definition should be applied.), undergoing at least 4 months of common therapies without significant response. Exclusion criteria: Possible drug side effects, no compliance for follow up

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

Gender
Both

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Triple blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences

Street address
Khorram St., Isfahan, Iran

City
Isfahan

Postal code

Approval date
2007-03-10, 1385/12/19

Ethics committee reference number
387198

Health conditions studied

1

Description of health condition studied
Metabolic Syndrome

ICD-10 code
E78.8

ICD-10 code description
Other disorders of lipoprotein metabolism

Primary outcomes

1

Description
Waist circumference

Timepoint
At the beginning of the study and 8 weeks after intervention.

Method of measurement
Non elastic tape with accuracy of 0.1 cm

2

Description
Weight

Timepoint
at the beginning of the study and 8 weeks after intervention

Method of measurement
SECA medical scale with the accuracy of o.1 kg

3

Description
Height

Timepoint
at the beginning of the study

Method of measurement
SECA stadiometer with the accuracy of 0.1 cm

4

Description
Triglycerides(TG)

Timepoint
At the beginning of the study and 8 weeks after intervention.

Method of measurement
Enzymatic

5

Description
Blood pressure

Timepoint
At the beginning of the study and 8 weeks after intervention.

Method of measurement
Mercury sphygmomanometer wit the accuracy of 1mmHg

6

Description
High-density lipoprotein (HDL)

Timepoint
At the beginning of the study and 8 weeks after intervention.

Method of measurement
Enzymatic

7

Description
Fasting Blood Sugar(FBS)
Timepoint
At the beginning of the study and 8 weeks after intervention.
Method of measurement
Glucose Oxidase method

8

Description
BMI
Timepoint
At the beginning of the study and 8 weeks after intervention.
Method of measurement
calculated by the formula:weight/height2(kg/m2)

Secondary outcomes

1

Description
Total cholesterol
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
Enzymatic

2

Description
Low Density Lipoprotein(LDL)
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
Directly

3

Description
Nitric Oxide(NO)
Timepoint
At the begining of intervention and 8 weeks later
Method of measurement
ELISA

4

Description
Vascular Endothelial Growth Factor(VEGF)
Timepoint
At the begining of intervention and 8 weeks later
Method of measurement
Sandwich ELISA method

5

Description
Fasting Insulin
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
ELISA

6

Description
Total Anti Oxidant Capacity in Plasma
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
calorimetery

7

Description
HOMA-IR
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
calculation

8

Description
hs-CRP
Timepoint
At the beginning of the study and 8 weeks after intervention
Method of measurement
Immunoturbidimetry

Intervention groups

1

Description
Omega-3 Capsule, 2000 mg (containing 600 mg EPA/DHA) once daily for 8 weeks
Category
Treatment - Drugs

2

Description
Vitamin E capsule, 400 IU once daily for 8 weeks
Category
Treatment - Drugs

3

Description
Placebo capsule once daily for 8 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Isfahan Cardiovascular Research Center
Full name of responsible person
Roya Kelishadi, MD
Street address
Khorram St.
City
Isfahan
City
Isfahan
Postal code
Phone
+98 31 1337 7881
Fax
+98 31 1337 3435
Email
kelishadi@med.mui.ac.ir
Web page address
www.crc.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellery for Research, Isfahan University of Medical Sciences
Full name of responsible person
Peyman Adibi, MD
Street address
Hezar Jarib St.
City
Isfahan
Grant name
Grant code / Reference number
387198
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellery for Research, Isfahan 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
Name of organization / entity
Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences
Full name of responsible person
Roya Kelishadi
Position
Associate Professor
Other areas of specialty/work
Street address
Khorram St.

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences
Full name of responsible person
Roya Kelishadi
Position
Associate Professor
Other areas of specialty/work
Street address
Khoram st., Isfahan, Iran
City
Isfahan
Postal code
Phone
+98 31 1337 7881
Fax
Email
kelishadi@med.mui.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Full name of responsible person
Roya Kelishadi, MD
Position
Other areas of specialty/work
Street address
City
Postal code
Phone
Fax
Email
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