

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of supplementation with iron alone and combined with the docosahexaenoic acid and changes in serum lipid profile on risk of Coronary- heart disease via measuring paraoxonase 1, hs-CRP and the ApoB / ApoA1 ratio in women with iron deficiency anemia

Protocol summary

Summary

This study with the aim of the definition of The effect of supplementation with iron alone and combined with the docosa hexaenoic acid and changes in serum lipid profile on risk of Coronary- heart disease via measuring paraoxonase 1, hs-CRP and the ApoB / ApoA1 ratio in women with iron deficiency anemia carried in a Randomized placebo-controlled double-blind Clinical trial In a period of 21 months in women 15-45 years of age with iron deficiency anemia. Among of patients were willing to cooperate, Background, anthropometric, biochemical and dietary intake and physical activity will be assessed. to And if having Serum ferritin less than 12 $\mu\text{g} / \text{l}$ and serum iron of 60 $\text{mcg}/100\text{ml}$ and don't have diabetes, thalassemia, history of peptic ulcer disease or malabsorption and lack of blood transfusions in the past 2 months, 80 patients are enrolled . Of the two groups receiving supplemental DHA + ferrous sulfate or placebo + ferrous sulfate into each day, 1 capsule of 500 mg DHA or placebo, with a tablet inserted sulfate contains 50 mg of elemental iron for 12 weeks taking . From 24-hour dietary recalls at baseline and end of study to be taken daily intake of calories, carbohydrates, fat, protein, fiber and antioxidants, especially vitamins A, C and E, beta carotene, zinc, selenium, iron, copper, Sodium, potassium and dietary fat type is specified. In the study cardiovascular disease is evaluated by measuring paraoxonase 1, hs-CRP and the ApoB / ApoA1 and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301182709N27**

Registration date: **2013-03-24, 1392/01/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-03-24, 1392/01/04

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences & Health Services

Expected recruitment start date

2013-04-04, 1392/01/15

Expected recruitment end date

2013-10-07, 1392/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supplementation with iron alone and combined with the docosahexaenoic acid and changes in

serum lipid profile on risk of Coronary- heart disease via measuring paraoxonase 1, hs-CRP and the ApoB / ApoA1 ratio in women with iron deficiency anemia

Public title

The effect of iron and omega-3 on coronary heart disease

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: • Serum ferritin less than 12 µg / l and serum iron of 60 mcg/100ml • Women in the range of 15 to 45 years of age • regular menstrual cycles • willingness to cooperate and fill the criteria of informed consent form to the project exclusion criteria: • smoking tobacco or alcohol • iron supplements, multivitamins and antioxidants in the last three months • the use of lipid-lowering drugs, oral contraceptives • the use of oral contraceptives • parasitic infections (those who have been diagnosed positive stool test will be excluded.) • thalassemia disease • kidney disease, liver disease, diabetes • local or systemic infection or inflammatory disease • history of ulcer disease or gastrointestinal bleeding or fibroids • malabsorption such as celiac sprue or steatorrhea • Any type of blood transfusion in the last 2 months of • pregnancy or lactation • not wanting to continue working • inadequate compliance supplement (compliance less than 80%) • change in diet or physical activity for any reason

Age

From 15 years old to 45 years old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

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

Tehran University of Medical Sciences & Health Services

Street address

Tehran, Department of Nutrition and Diet, Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2013-02-18, 1391/11/30

Ethics committee reference number

78699-20450-161-04-91

Health conditions studied

1

Description of health condition studied

Iron deficiency anaemia

ICD-10 code

D50.9

ICD-10 code description

Iron deficiency anaemia, unspecified

2

Description of health condition studied

Iron deficiency anaemia

ICD-10 code

D50.8

ICD-10 code description

Other iron deficiency anaemias

Primary outcomes

1

Description

Fasting serum ferritin

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

According µg / l Lyazvn method

2

Description

Paraoxonase 1 activity

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

By U / L spectrophotometry

3

Description

Fasting serum ApoB levels

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

Based on Mg / dl Turbydymtry method

4

Description

Fasting serum concentrations of ApoA1

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

Based on Mg / dl Turbidity method

5

Description

fasting concentrations of serum HS-CRP

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

Based on Mg / l immunohistochemical method Fluorimetry

6

Description

Fasting serum iron

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

According to mg / dl spectrophotometry

Secondary outcomes

1

Description

body mass index

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Kg/m² calculated based on the height and weight

2

Description

age

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

In terms of the question

3

Description

energy intake

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (kcal / day) over a 24-hour dietary questionnaire.

4

Description

Carbohydrate intake

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (g/day) over a 24-hour dietary questionnaire.

5

Description

Protein intake

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (g/day) over a 24-hour dietary questionnaire.

6

Description

fat intake

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (g/day) over a 24-hour dietary questionnaire.

7

Description

fiber intake

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (g/day) over a 24-hour dietary questionnaire.

8

Description

vitamin A

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

9

Description

vitamin C

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

10

Description

vitamin E

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

11

Description

Betacarotene

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

12

Description

iron

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

13

Description

zinc

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

14

Description

Selenium

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

15

Description

Copper

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

16

Description

Sodium

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

17

Description

Potassium

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

18

Description

kind of fat

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

Terms (mg/day) over a 24-hour dietary questionnaire.

19

Description

Level of physical activity

Timepoint

Before the experiment, 12 weeks after intervention

Method of measurement

In terms of intensity (light, medium and heavy) information through a questionnaire

Intervention groups

1

Description

Group of intervention: Patients with iron deficiency anemia that is based on sharing random daily receive capsule supplement DHA-containing (465 mg DHA + 63 mg EPA) + a tablet into sulfate containing 50 mg elemental iron for 12 weeks .

Category

Treatment - Drugs

2

Description

Group or the control pf: People with iron-deficiency anemia that is based on sharing a random day a number of placebo capsules containing 500 mg of corn oil + a tablet of sulfate contains 50 mg of elemental iron for 12 weeks to receive .

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Samira Amani

Street address

City

Ghaemshahr

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences and Health services

Full name of responsible person

Doctor Akbar Fotouhi

Street address

Central Organization of Tehran University, Qods St, Keshavarz Blvd

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
 Yes
Title of funding source
 Tehran University of Medical Sciences and Health services
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

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Web page address

Person responsible for updating data

Contact

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