Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 women15-45 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 µg / l and serum iron of 60 mcg/100ml 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

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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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 µ g / 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 µ g / 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 Turbydymtry 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 Flumtryk

6

Description
Fasting serum iron
Timepoint
before the experiment.12 weeks after intervention
Method of measurement
According μ g / 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 df or 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

Contact
Name of organization / entity
Tehran University of Medical Therapy
Full name of responsible person
Samira Amani
Position
Student Nutrition
Other areas of specialty/work
Street address
not the bottom left deadlocked belt last, Alley Rajai martyr, Tehran St, Ghaemshahr, Mazandaran, Iran
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences and Health Services
Full name of responsible person
F. Shidfar doctor
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PhD Nutrition Sciences
Other areas of specialty/work
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City
Tehran
Postal code
Phone
+98 21 8877 9118
Fax
Email
f-shidfar@tums.ac.ir
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