Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of supplementation with iron alone and combined with the docosahexaenoic acid on iron deficiency anemia index and oxidative stress 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 docosahexaenoic acid on iron deficiency anemia index and oxidative stress 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 Hb> g / dl 12, HCT <35% and transferrin saturation less than 15% 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. The study measured levels of oxidative stress, catalase, MDA, triglycerides and HDL can be measured and compared in the two groups.

General information

Acronym

DHA : docosahexaenoic acid

IRCT registration information

IRCT registration number: **IRCT201210252709N26**
Registration date: **2013-01-22, 1391/11/03**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-01-22, 1391/11/03

Registrant information

Name
Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 21 8862 2755
Email address
shidfar.f@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences & Health Services

Expected recruitment start date

2012-11-22, 1391/09/02

Expected recruitment end date

2013-10-24, 1392/08/02

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 on iron deficiency anemia index and oxidative stress in women with iron deficiency anemia

Public title

Effects of Omega-3 on the iron deficiency anemia

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: • Hemoglobin> g / dl 12, HCT <35% and transferrin saturation less than 15% • 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, Faculty of Health, Tehran University of Medical Sciences

City

Tehran

Postal code

Approval date

2012-04-08, 1391/01/20

Ethics committee reference number

2570/130/90/ɔ

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

catalase

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

by k/gHb spectrophotometry

2

Description

malondialdehyde

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

by Nmol/ml theobarbituryk acid method

3

Description

triglycerides

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

by Mg/dl colorimetric method

4

Description

high density lipoprotein

Timepoint

before the experiment.12 weeks after intervention

Method of measurement

by Mg/dl enzymetic method

5

Description
Blood hemoglobin
Timepoint
Before the experiment, 12 weeks after intervention
Method of measurement
Based on Mg / dl using cell counter machine

6

Description
Fasting serum iron
Timepoint
Before the experiment, 12 weeks after intervention
Method of measurement
According µ g / dl spectrophotometry

7

Description
Total iron binding capacity
Timepoint
Before the experiment, 12 weeks after intervention
Method of measurement
According µ g / dl spectrophotometry

8

Description
Mean corpuscular volume
Timepoint
Before the experiment, 12 weeks after intervention
Method of measurement
based on (Fl) calculated by the formula

9

Description
Mean Corpuscular Hemoglobin Concentration
Timepoint
Before the experiment, 12 weeks after intervention
Method of measurement
based on (g/dl) calculated by the formula

10

Description
hematocrit
Timepoint
Before the experiment, 12 weeks after intervention
Method of measurement
Percent to the cell counter

11

Description
Transferrin saturation
Timepoint
Before the experiment, 12 weeks after intervention
Method of measurement
Based on the percentage determined by the formula

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 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

2

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

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, GhaemshahrMazandaran, Iran

City

Ghaemshahr

Postal code

Phone

+98 12 3237 0630

Fax

Email

s.amani5n@gmail.com

Web page address

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

Position

PhD Nutrition Sciences

Other areas of specialty/work

Street address

Tehran University of Medical Sciences, Faculty of Health, Tehran

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