Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effects of vitamin D or iron-vitamin supplementation on bone metabolism and inflammation in 18-40-year women

Protocol summary

Summary

The present study will investigate the effects of vitamin D supplementation alone or in combination with iron on bone metabolism and inflammation in women. The inclusion criteria will be simultaneous anemia and vitamin D deficiency. Subjects will be excluded if they have hematologic diseases. Ninety women (aged 18-40) will be randomly assigned to one of two treatments: 1000IU vitamin D plus 27mg elemental iron or 1000IU vitamin D plus placebo every day for 3 months. Blood samples will be collected at baseline and the end of the study and stored at -80 oC. They will be asked to complete a 3 days food record and physical activity questionnaire at the beginning, middle and end of the study. To assess the effect of intervention on anxiety and depression, the Beck Depression Inventory will be used. Blood pressure, body weight, and height will be measured, too. Blood venous samples will be taken after 12hr fasting. CBC, Ferritin, Serum iron, Transferrin, Ttransferrin saturation, OC, PTH, CTx, ALP, 25(OH)D, TIBC, and hsCRP will be assessed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409082365N9**
Registration date: **2014-10-27, 1393/08/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-27, 1393/08/05

Registrant information

Name

Mohammad Reza Vafa

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2014-10-11, 1393/07/19

Expected recruitment end date

2014-11-10, 1393/08/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of vitamin D or iron-vitamin supplementation on bone metabolism and inflammation in 18-40-year women

Public title

The effect of vitamin D plus iron vs. vitamin D on bone health and inflammation in women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Healthy; Non-smoker; Non-pregnant; Non-lactating; Body mass index: 18.5-29.9 kg/m2; Ferritin less than 30 ng/ml; Hemoglobin less than 12 g/dl; 25 hydroxy vitamin D less than 30 ng/ml. Exclusion criteria: Amenorrhea; Menopause; Minor Thalasemia; Hemochromatosis; Inflammatory bowel diseases; Crohn's

disease; Gastric ulcer; Celiac disease; Gastrointestinal bleeding diseases; Renal diseases; Blood donation during past 3 months; Iron or Vitamin D supplement use during past 3 months.

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

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 at Isfahan University of Medical Sciences

Street address
Isfahan University Of Medical Sciences, Isfahan, Iran

City
Isfahan

Postal code
81754

Approval date
2014-09-07, 1393/06/16

Ethics committee reference number
D/98/340

Health conditions studied

1

Description of health condition studied
Association between iron supplementation and vitamin D or vitamin D alone on bone metabolism and inflammation in women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
25 hydroxy vitamin D

Timepoint
At baseline and the end of the study

Method of measurement
Blood sample

Secondary outcomes

1

Description
Hematocrit

Timepoint
At baseline and the end of the study

Method of measurement
Blood sample

2

Description
Mean Cell Vollum

Timepoint
At baseline and the end of the study

Method of measurement
Blood sample

3

Description
Hemoglobin

Timepoint
At baseline and the end of the study

Method of measurement
Blood sample

4

Description
Serum iron

Timepoint
At baseline and the end of the study

Method of measurement
Blood sample

5

Description
Ferritin

Timepoint
At baseline and the end of the study

Method of measurement
Blood sample

6

Description
Transferrin

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

7

Description

Transferrin saturation

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

8

Description

Total Iron Binding Capacity

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

9

Description

Alkaline phosphatase

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

10

Description

Parathyroid hormone

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

11

Description

C-terminal telopetide x

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

12

Description

Osteocalcin

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

13

Description

Highly-sensitive C Reactive Protein

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

14

Description

Tumor Necrosis Factor Alpha

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

15

Description

Interleukin 6

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

16

Description

Total Antioxidant Capacity

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

17

Description

Malodialdehyde

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

18

Description

Lipid profile

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

19

Description

Fasting Blood Sugar

Timepoint

At baseline and the end of the study

Method of measurement

Blood sample

Intervention groups

1

Description

Intervention group participants will be prescribed two

tablets (one 1000 international unit vitamin D plus one 27 mg elemental iron every day). They will instructed to take the tablets separately.

Category

Treatment - Drugs

2

Description

Control group participants will be prescribed two tablets (one 1000 international unit vitamin D plus one placebo every day). They will instructed to take the tablets separately.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran University of Medical Sciences faculties and dorms

Full name of responsible person

Dr Mohammadreza Vafa

Street address

Nutrition and health group, Faculty of health, Iran University of Medical Sciences, Hemmat highway, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Dr Sayyed Morteza Safavi

Street address

Department of clinical nutrition, School of Nutrition and Food Sciences, Isfahan University of Medical Sciences, Isfahan, Iran

City

Isfahan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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

Nutrition and health group

Full name of responsible person

Dr Mohammadreza Vafa

Position

PhD of nutrition, Professor

Other areas of specialty/work

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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