

# 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)

##### Phone

+98 21 8670 4734

##### Email address

vafa.m@iums.ac.ir

##### 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/m<sup>2</sup>; 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 Volumn

**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 telopeptide 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 be 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 be 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****Street address**

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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*