

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of vitamin D supplementation on metabolic syndrome Components in Military with metabolic syndrome

#### Protocol summary

2015-01-09, 1393/10/19

#### Summary

In this study military individuals who their waist circumference is greater than or equal to 80 cm (for women) and greater than or equal to 94 cm (for men) will be referred to the laboratory to measure vitamin D and other factors necessary for the diagnosis of metabolic syndrome . Blood samples were collected in the laboratory to evaluate the lipid profiles and blood sugar . Blood pressure (average 2 seated blood pressure measurements)and vitamin D concentration were also measured.After evaluating of laboratory results, those with metabolic syndrome according to IDF criteria and also have vitamin D deficiency (serum 25-hydroxyvitamin D less than 20 ng ml) have been included, and base on exclusion criteria, will be selected. Then, based on a randomized block design will be assigned to intervention and control groups. Intervention group will receive vitamin D Pearl with dose of 50000IU once a week for 8 weeks, and control group will receive placebo one pearl weekly. After the intervention period , all the above mentioned measurements are performed again to evaluate the changes.Blinding to both patients and for researcher will be conducted.,Manufacture will offer vitamin D and placebo pearl as code A and B quite similar in appearance. neither patient nor researcher having information about pearl.

#### Registrant information

##### Name

Sepideh Abbaszadeh

##### Name of organization / entity

Baqiyatallah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8804 0153

##### Email address

abbaszadehs@bmsu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice Chancellor for research of Baqiyatallah University of Medical Sciences.

#### Expected recruitment start date

2014-12-11, 1393/09/20

#### Expected recruitment end date

2015-03-16, 1393/12/25

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of vitamin D supplementation on metabolic syndrome Components in Military with metabolic syndrome

#### Public title

Effect of Vitamin D on metabolic syndrome.

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria : military staff ; Metabolic Syndrome;

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014020211920N3**

Registration date: **2015-01-09, 1393/10/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

vitamin D deficiency exclusion criteria: Diabetes ;Thyroid disorders ;Liver disease ;Kidney disease; Pregnancy and lactation ;Developing chronic steatorrhea ;Cholecystectomy ; consumption vitamin D supplementation

#### Age

From **20 years** old to **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **56**

#### 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 of Baqiyatallah University of Medical Sciences

##### Street address

Baqiyatallah University of Medical Sciences, Molla Sadra street , Sheikh Bahaei street, Tehran, Iran

##### City

Tehran

##### Postal code

#### Approval date

2014-07-31, 1393/05/09

#### Ethics committee reference number

93/754ع

## Health conditions studied

### 1

#### Description of health condition studied

obesity

#### ICD-10 code

E66.0

#### ICD-10 code description

Obesity due to excess calories

### 2

#### Description of health condition studied

metabiloc syndrome

#### ICD-10 code

E78.8

#### ICD-10 code description

Other disorders of lipoprotein metabolism

### 3

#### Description of health condition studied

vitamin D deficiency

#### ICD-10 code

E55.9

#### ICD-10 code description

Vitamin D deficiency, unspecified

## Primary outcomes

### 1

#### Description

Triglycerides

#### Timepoint

befor and after intervention

#### Method of measurement

Milligrams per deciliter / enzymatic method using a kit

### 2

#### Description

Fasting blood glucose

#### Timepoint

befor and after intervention

#### Method of measurement

Milligrams per deciliter / enzymatically

## Secondary outcomes

### 1

#### Description

weight

#### Timepoint

befor and after intervention

#### Method of measurement

kg/Using a digital scale

### 2

#### Description

Length

#### Timepoint

befor and after intervention

#### Method of measurement

cm/using the meter

### 3

#### Description

Serum level of Vitamin D

#### Timepoint

Before and after the study

**Method of measurement**

Eliza

**4**

**Description**

Systolic blood pressure

**Timepoint**

Before and after the study

**Method of measurement**

Using a sphygmomanometer in the sitting position

**5**

**Description**

Dystolic blood pressure

**Timepoint**

before and after study

**Method of measurement**

Using a sphygmomanometer in the sitting position

**6**

**Description**

High-density lipoprotein

**Timepoint**

before and after study

**Method of measurement**

Calorimetry

**7**

**Description**

waist circumference

**Timepoint**

before and after study

**Method of measurement**

Using a tape measure in between the last rib, chest and navel waist measured.

**Intervention groups**

**1**

**Description**

Vitamin D supplementation in single pearl 50000 at 1 pill per week for 8 weeks ,(Totaling 300,000 units)

**Category**

Treatment - Drugs

**2**

**Description**

Placebo with vitamin D look like pearls ,1 pill weekly for 8 weeks will be given

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Fallahi Clinic

**Full name of responsible person**

Mohamad Amani

**Street address**

Department of Health and Relief Treatment Army, martyr clinic Fallahi, Lavizan, martyr Babaei Highway (East), Tehran

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

vice chancellor of Baqiyatallah University of Medical Sciences.

**Full name of responsible person**

Mr hoseinishokoh

**Street address**

Baqiyatallah University of Medical Sciences, Molla Sadra street , Sheikh Bahaei street, Tehran, Iran

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

vice chancellor of Baqiyatallah 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**

Department of Health and Relief Therapy Army

**Full name of responsible person**

Mohammad Amani

**Position**

MSc in Nutrition

**Other areas of specialty/work**

**Street address**

Department of Health and Relief Therapy Army, input Lavizan, martyr Babaei Highway (East), Tehran

**City**

Tehran

**Postal code****Phone**

+98 21 2295 1539

**Fax**

+98 22951926

**Email**

mo\_amani@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Baqiyatallah University of Medical Sciences

**Full name of responsible person**

Karim Parastouei

**Position**

PhD student in nutrition

**Other areas of specialty/work****Street address**

Baqiyatallah University of Medical Sciences, Molla Sadra street , Sheikh Bahaei street, Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8248 2467

**Fax****Email**

parastouei@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Department of Health and Relief Therapy Army

**Full name of responsible person**

Mohammad Amani

**Position**

MSc in nutrition

**Other areas of specialty/work****Street address**

Department of Health and Relief Therapy Army, input Lavizan, martyr Babaei Highway (East), Tehran

**City**

Tehran

**Postal code**

021

**Phone**

+98 21 2295 1539

**Fax****Email**

mo\_amani@yahoo.com

**Web page address****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*