

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

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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
befor and after study
Method of measurement
Using a sphygmomanometer in the sitting position

6

Description
High-density lipoprotein
Timepoint
befor and after study
Method of measurement
Calorimetry

7

Description
waist circumference
Timepoint
befor 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
vice chancellorof Baqiyatallah University of Medical Sciences.
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Baqiyatallah University of Medical Sciences, Molla Sadra street , Sheikh Bahaei street, Tehran, Iran
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
vice chancellorof 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
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Full name of responsible person

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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