

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effects of Vitamin D and Probiotic Co-Supplementation on metabolic syndrome components in the military personnel with this syndrome

#### Protocol summary

##### Study aim

Determining the effect of vitamin D supplementation and probiotic supplementation on the components of metabolic syndrome in soldiers with metabolic syndrome and using the results of this plan to use vitamin D and probiotic in the treatment of metabolic syndrome

##### Design

Intervention trial with control group and intervention group with factorial groups, double-blind, randomized, phase 4, on 60 patients,

##### Settings and conduct

People referring to the clinic of Khorram Asad Army Hospital. are researchers and participants in the blind study

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Metabolic syndrome according to IDF criteria  
Inclusion criteria: having a history of cardiovascular disease, liver and kidney failure, kidney, alcohol and smoking, pregnant women, taking probiotic or vitamin D supplements in the last three months

##### Intervention groups

One of the groups of vitamin D for 50,000 units a week number (for 8 weeks), with capsules of probiotics day one capsule (8 weeks) will be given to groups versus placebo for them, for Pearl One a week or one capsule a day will be prescribed

##### Main outcome variables

Systolic and diastolic blood pressure, HDL cholesterol, triglycerides, fasting blood sugar, waist size,

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180201038585N7**

Registration date: **2020-10-27, 1399/08/06**

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

Last update: **2020-10-27, 1399/08/06**

Update count: **0**

##### Registration date

2020-10-27, 1399/08/06

##### Registrant information

###### Name

Karim Parastouei

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8248 3516

###### Email address

parastouei@bmsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-01-19, 1399/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effects of Vitamin D and Probiotic Co-Supplementation on metabolic syndrome components in the military personnel with this syndrome

##### Public title

The Effects of Vitamin D and Probiotic on metabolic syndrome

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age 20-50 years With metabolic syndrome according to IDF criteria

**Exclusion criteria:**

Having a history of cardiovascular disease Hepatic and renal failure Alcohol and smoking pregnant women Use a probiotic supplement or vitamin D in the last three months

**Age**

From **20 years** old to **50 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization was performed by block randomization method which were matched by age an sex. Random sequence generation was done using table of random numbers by a third trained person. Allocation concealment was performed using sealed envelopes.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Intervention and assignment was performed by a third trained non-investigator person. The investigator and the participants were not aware of the allocation and will remain the same till the end of the study.

**Placebo**

Used

**Assignment**

Factorial

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of bahgeyatlah University of Medical Sciences

**Street address**

Sheykh Bahaei Ave, Molasadra Ave Vanak Square, Mulla Sadra St., South Sheikh Baha'i St.

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Approval date**

2020-08-19, 1399/05/29

**Ethics committee reference number**

IR.BMSU.REC.1399.330

**Health conditions studied****1****Description of health condition studied**

Metabolic syndrome

**ICD-10 code**

E88.81

**ICD-10 code description**

Metabolic syndrome

**Primary outcomes****1****Description**

Components of Metabolic Syndrome

**Timepoint**

At the beginning of the study and 56 days after weekly intake of vitamin D and daily probiotic capsules

**Method of measurement**

Using height and weight measuring instruments and meters and special test kits

**Secondary outcomes****1****Description**

Components of Metabolic Syndrome

**Timepoint**

At the beginning of the study and 56 days after the intervention

**Method of measurement**

Using height and weight measuring instruments and meters and special test kits

**Intervention groups****1****Description**

Intervention group: Intervention group: 8 weeks receiving PerI 50,000 units of vitamin D once a week and probiotic capsules once a day

**Category**

Treatment - Drugs

**2****Description**

Control group: 8 weeks receiving placebo (placebo) Pearl Vitamin D once a week and probiotic capsule placebo once a day

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Khorramabad Army Hospital Clinic

**Full name of responsible person**

Hamze Kakavand

**Street address**

Badrabad

**City**

Khorramabad

**Province**

Lorestan

**Postal code**

6914147631

**Phone**

+98 66 3347 0526

**Email**

hamzekakavand96@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Karim parastouei

**Street address**

South Sheikh Bahai St, Mollasadra Ave, Vanak Sq, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

912700255

**Phone**

+98 21 8804 0060

**Email**

parasstouei@bmsu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Bagheiat-allah University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

karim parastouei

**Position**

Associate professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Mullasadra Ave, Vannak Sq, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

9125007002

**Phone**

+98 21 8248 3516

**Email**

parastouei@bmsu.ac.ir

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Karim Parastouei

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Mullasadra Ave, Vannak Sq, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Phone**

+98 21 8804 0060

**Email**

parastouei@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Karim Parastouei

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Mullasadra Ave, Vannak Sq, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1435916471

**Phone**

+98 21 8248 3264

**Fax**

+98 21 8862 0842

**Email**

parastouei@bmsu.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

All data can be shared after identifying individuals.

**When the data will become available and for how long**

Access period starts 6 months after the results are published.

**To whom data/document is available**

It will be available only to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Statistical analysis is allowed on the documents and can be used after the data is published.

**From where data/document is obtainable**

En Email the project executor. parastouei@bmsu.ac.ir

**What processes are involved for a request to access data/document**

After receiving the email, the documents will be sent to the person within a maximum of one week.

**Comments**