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 Abad 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 Perl 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

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Iran (Islamic Republic of)

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+98 21 8248 3516

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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 Perl 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

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Province

Lorestan

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6914147631

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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

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

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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

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

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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