

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of synbiotic supplement on metabolic syndrome components in military personnel with this syndrome

Protocol summary

Study aim

The effect of synbiotic supplement on metabolic syndrome components in military personnel with this syndrome

Design

Randomised Clinical trial, parallel group, double blind

Settings and conduct

The aim of this study is to determine the effect of synbiotic supplement on the metabolic syndrome components in military personnel with this syndrome, Valiasr Hospital, Tehran. This study is a double blind Randomised clinical trial . Sixty patients suffering from metabolic syndrome assigned randomly into two groups: 1- Sinobiotic supplementation group(one supplement / day for 8 weeks) (intervention group) 2- Placebo (control group). Before and after the intervention, weight, BMI, WC, FBS, HDL, TG and blood pressure will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age (20-50 years) and According to the definition by IDF: Military personnel have the metabolic syndrome if the following criteria is met:Central obesity: waist circumference ≥ 94 Cm in Men and ≥ 80 Cm in women, plus any two of the following four components:triglyceride level: ≥ 150 mg/dl; HDL cholesterol: ≤ 50 in men and ≤ 40 mg/dl in women; blood pressure: $\geq 130/85$ mmHg; fasting plasma glucose: ≥ 100 mg/dl Exclusion criteria Having a history of cardiovascular disease, liver and kidney problems, alcohol and smoking, and postmenopausal women

Intervention groups

Patients with Metabolic Syndrome

Main outcome variables

Waist circumference; HDL; TG; FBS and blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140502017522N3**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **prospective**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

Registration date

2019-03-16, 1397/12/25

Registrant information

Name

Maryam Taghdir

Name of organization / entity

Baqiyatallah University of medical sciences

Country

Iran (Islamic Republic of)

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+98 21 8755 5511

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mtaghdir@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of synbiotic supplement on metabolic syndrome components in military personnel with this syndrome

Public title

The effect of synbiotic supplement on metabolic syndrome components in military personnel with this syndrome

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age (20-50 years) and According to the definition by IDF: Military personnel have the metabolic syndrome if the following criteria is met: Central obesity: waist circumference ≥ 94 Cm in Men and ≥ 80 Cm in women, plus any two of the following four components: triglyceride level: ≥ 150 mg/dl; HDL cholesterol: ≤ 50 in men and ≤ 40 mg/dl in women; blood pressure: $\geq 130/85$ mmHg; fasting plasma glucose: ≥ 100 mg/dl.

Exclusion criteria:

Having a history of cardiovascular disease, liver and kidney problems alcohol and smoking, postmenopausal women.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 military personnel simple randomized to two groups A and B using the table of random numbers . Only the company knows the contents of the supplements and names the supplements as A and B.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant and investigator

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Baqiyatallah University of Medical Sciences

Street address

Baqiyatallah University of Medical sciences, Bahae street, Mollasadrai Avenue, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2019-01-21, 1397/11/01

Ethics committee reference number

IR.Bmsu.REC.1397.148

Health conditions studied

1

Description of health condition studied

Metabolic syndrome

ICD-10 code

(E00-E90)

ICD-10 code description

Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description

Body mass index(BMI)

Timepoint

2 times: 1. Before supplementation 2. After 8 weeks

Method of measurement

Wt(Kg)/Ht(m²)

2

Description

Fasting blood sugar(FBS)

Timepoint

2 times: 1. Before supplementation 2. After 8 weeks

Method of measurement

In mg / dl using an autoanalyzer device

3

Description

blood pressure(BP)

Timepoint

2 times: 1. Before supplementation 2. After 8 weeks

Method of measurement

Using the blood pressure device in mm / hg

4

Description

HDL cholesterol

Timepoint

2 times: 1. Before supplementation 2. After 8 weeks

Method of measurement

In mg / dl using auto-analyzer

5

Description

Tri glyceride

Timepoint

2 times: 1. Before supplementation 2. After 8 weeks

Method of measurement

In mg / dl and using auto-analyzer

6

Description

Waist circumference

Timepoint

2 times: 1. Before supplementation 2. After 8 weeks

Method of measurement

Measured with meter

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: one synbiotic capsule per day for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: one placebo per day for 8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital, NAJA

Full name of responsible person

Dr Maryam Taghdir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Sahar Saeidipoor

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Not applicable