

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

The effect of vitamin B1 (thiamine) on blood pressure, lipid profile, liver enzymes and fasting blood sugar in patients with metabolic syndrome

Protocol summary

Study aim

Effect of vitamin B1 (thiamine) on blood pressure, lipid profile, liver enzymes, fasting blood sugar, metabolic syndrome patients in military patients referred to 525(khorramabad) Army Hospital

Design

This study was performed as randomized, parallel controlled clinical trial on 116 patients with Mets

Settings and conduct

This study was performed as randomized, parallel controlled clinical trial on 116 patients with Metabolic Syndrome. In this study, while receiving written informed consent from patients, participants were blinded to receiving drugs and placebo.

Participants/Inclusion and exclusion criteria

Age range for the present study 25 to 50 years is considered and accordingly, subjects that aged 25- 50 years, and according to IDF criteria, waist circumference shall be equal to or greater than 94 and 80 cm in men and women, respectively. In addition to waist circumference, if candidates meet two of the following 4 criteria, they will be diagnosed with MetS: Fasting blood sugar above 100 mg / dl Triglycerides equal to or greater than 150 mg / dL Blood pressure equal to or greater than 135/85 mm Hg HDL less than 40 and 50 mg / dl in men and women, respectively No admittance and exclusion criteria from study History of cardiovascular disease Hepatic, renal and metabolic disorders Alcohol , cigarettes, supplements and certain drugs consumption People who during the study less than 80% of the tablets vitamin b1 (thiamin) and placebo to consume

Intervention groups

Participants into two categories consumer vitamin b1 and placebo divided

Main outcome variables

Indicators of profail lipidi(TG-Chol-HDL-LDL) , liver enzymes(ALT- AST), fasting blood suger, blood perser systolic ,blood perser diastolic

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180201038585N5**

Registration date: **2019-11-10, 1398/08/19**

Registration timing: **registered_while_recruiting**

Last update: **2019-11-10, 1398/08/19**

Update count: **0**

Registration date

2019-11-10, 1398/08/19

Registrant information

Name

Karim Parastouei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8248 3516

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parastouei@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-17, 1398/07/25

Expected recruitment end date

2019-12-16, 1398/09/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vitamin B1 (thiamine) on blood pressure, lipid profile, liver enzymes and fasting blood sugar in patients with metabolic syndrome

Public title

The effect of vitamin B1 (thiamine) on blood pressure, lipid profile, liver enzymes and fasting blood sugar in the military with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age: 25 -50 years Military personnel with metabolic syndrome

Exclusion criteria:

Having a history of cardiovascular disease morbidity liver, kidney Consumption alcoho, smoking ,supplementation and certain drugs People who during the study less than 80% of the tablets vitamin b1 and placebo to consume.

Age

From **25 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple dice randomization method was used in which paired numbers for the intervention group and individual numbers for the control group were used.

Blinding (investigator's opinion)

Double blinded

Blinding description

Intervention and randomization were performed through a random allocation list by a member of the research team as the only blinded individual to the assignment. Other members of the research team (including team leader and study coordinator), as well as all participants, were randomly assigned to groups and intervention and remained blind until the end of the study.

Placebo

Used

Assignment

Parallel

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

Moulla Sadra Ave , Vannak Square

City

Tehran

Province

Tehran

Postal code

1435916471

Approval date

2019-08-27, 1398/06/05

Ethics committee reference number

IR.BMSU.REC.1398.240

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

fasting blood sugar

Timepoint

before intervention and end of intervention

Method of measurement

Lab kit

2

Description

Triglyceride

Timepoint

before intervention and end of intervention

Method of measurement

Lab kit

3

Description

cholesterol

Timepoint

before intervention and end of intervention

Method of measurement

Lab kit

4

Description

blood presure

Timepoint

before intervention and end of intervention

Method of measurement

Lab kit

5

Description

Alanin transfrase

Timepoint

before intervention and end of intervention

Method of measurement

Lab kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Vitamin B1, 100 mg, every day, darou pakhsh

Category

Treatment - Drugs

2

Description

Control group: Placebo

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Khorramabad Army Hospital

Full name of responsible person

Yaser Souri

Street address

5 km of Khorramabad-Andimeshk Highway

City

Khorramabad

Province

Lorestan

Postal code

6812345678

Phone

+98 66 3347 0525

Email

arvin.souri@gmail.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ali Shiri

Street address

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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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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

Because of the confidentiality of the information on the civilians

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available