

# 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

##### Email address

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

**City**

Tehran

**Province**

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1435915371

**Phone**

+98 21 8248 3516

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arvin.souri@gmail.com

**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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karimparastouei@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Karim Parastouei

**Position**

Associate Professor

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## Person responsible for updating data

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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