

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### The effect of curcumin, coenzyme Q10 and their combined effects on metabolic syndrome components in soldiers with metabolic syndrome

#### Protocol summary

##### Study aim

The effect of Curcumin, Coenzyme Q10 and Their Combinations on Metabolic Syndrome Components in soldiers with Metabolic Syndrome

##### Design

this study was performed as randomized, parallel controlled clinical trial on 88 patients with Metabolic Syndrome

##### Settings and conduct

this study was performed as randomized, parallel controlled clinical trial on 88 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

The age range for the current study is between 30 and 50 years, and based on the age range of 30 to 50 years old, IDF has a waist circumference of more than 94 cm and 2 criteria of 4 The following criteria will be diagnosed with metabolic syndrome: fasting blood glucose greater than 100 mg / dL, triglyceride greater than 150 mg / dL, blood pressure greater than 130/85 mm Hg, and lower HDL From 40 mg / dl

##### Intervention groups

Patients were divided into three groups of intervention and one control group. The intervention group with curcumin, The intervention group with CoQ10, The intervention group with curcumin and CoQ10 and placebo group

##### Main outcome variables

indicators of profail lipidi(tg-chol-hdl-ldl) indicators of antropometric(bmi-waist-wighet) fasting blood suger blood perser systolic ,blood perser diastolic

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180201038585N2**

Registration date: **2018-09-21, 1397/06/30**

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

Last update: **2018-09-21, 1397/06/30**

Update count: **0**

##### Registration date

2018-09-21, 1397/06/30

##### 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

2018-07-19, 1397/04/28

##### Expected recruitment end date

2018-12-28, 1397/10/07

##### Actual recruitment start date

2018-07-23, 1397/05/01

##### Actual recruitment end date

2019-01-21, 1397/11/01

##### Trial completion date

empty

##### Scientific title

The effect of curcumin, coenzyme Q10 and their combined effects on metabolic syndrome components in soldiers with metabolic syndrome

##### Public title

Effect of curcumin, coenzyme Q10 and their combined effects on metabolic syndrome components in soldiers with metabolic syndrome

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

age: 30 -50 years military personnel with metabolic syndrome

##### **Exclusion criteria:**

the use of statins in the last 3 months having a history of cardiovascular disease morbidity liver, kidney Consumption alcohol and smoking supplementation and certain drugs people who have taken less than 80% of the capsules containing curcumin, quinidine Q10 and placebo.

#### **Age**

From **30 years** old to **50 years** old

#### **Gender**

Male

#### **Phase**

3

#### **Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

#### **Sample size**

Target sample size: **88**

Actual sample size reached: **88**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Simple random method has been used

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

Intervention and randomization through a random allocation list was made by a member of the research team as the only non-blind person to be assigned. Other team members (including team leader and study coordinator) as well as all participants, were randomly allocated to blind groups 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**

Vanak - Mulla Sadra Street

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1435916471

##### **Approval date**

2018-06-30, 1397/04/09

##### **Ethics committee reference number**

IR.Bmsu.rec.1397.449

### **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**

waist circumference

##### **Timepoint**

before intervention and end of intervention

##### **Method of measurement**

measuring tape

#### **2**

##### **Description**

fasting blood sugar

##### **Timepoint**

before intervention and end of intervention

##### **Method of measurement**

lab kit

#### **3**

##### **Description**

Triglyceride

##### **Timepoint**

before intervention and end of intervention

##### **Method of measurement**

lab kit

#### **4**

##### **Description**

cholesterol

##### **Timepoint**

before intervention and end of intervention

##### **Method of measurement**

lab kit

## 5

### Description

blood pressure

### Timepoint

before intervention and end of intervention

### Method of measurement

sphygmomanometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 1, curcumine 500mg, Every other day, Karen co.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: 2, CoQ10, 60mg, once a ,day , nature made

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group:3, combination of (curcumine 500mg, Every other day, CoQ10, 60mg, once a ,day)

#### Category

Treatment - Drugs

### 4

#### Description

Control group: placebo

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Health, Assistance and Treatment of Police

##### Full name of responsible person

javad mirahmadi

##### Street address

Department of Health, Assistance and Treatment of Police, Enghelab square, Tehran, Iran

##### City

Tehran

#### Province

Tehran

#### Postal code

1435915371

#### Phone

+98 21 6398 2262

#### Email

javadmirahmadinut@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Bagheiat-allah University of Medical Sciences

##### Full name of responsible person

Dr. Alishir

##### Street address

Mollasadra St, Vanak Sq, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1435915371

##### Phone

+98 21 8248 3516

##### Email

javadmirahmadinut@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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**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