

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Investigating the effect of zinc supplementation on the levels of oxidative stress and inflammation markers and glucose homeostasis in overweight or obese patients with metabolic syndrome

#### Protocol summary

##### Study aim

Investigating the effect of zinc supplementation on the levels of oxidative stress and inflammation markers and glucose homeostasis in overweight or obese patients with metabolic syndrome

##### Design

In this clinical trial, which is a prospective, randomized, controlled, parallel and double-blind study, 60 patients with metabolic syndrome will be selected. Patients are divided into two groups A (30 patients) and B (30 patients) based on admission number and using a table of random numbers.

##### Settings and conduct

The location of the study will be Dr. Shakri's clinic in Bojnord, North Khorasan. The field of study is the findings of previous studies about the antidiabetic effects of zinc. Blinding is done to the clinical doctor and the studied patients.

##### Participants/Inclusion and exclusion criteria

Patients over 18 to 70 years old with metabolic syndrome  
Inclusion criteria: Overweight or obesity (BMI above 25)  
Exclusion criteria: Taking zinc supplements for at least three months before the start of the study

##### Intervention groups

Patients with metabolic syndrome receiving zinc supplementation, patients with metabolic syndrome receiving placebo

##### Main outcome variables

Levels of markers of oxidative stress and inflammation and glucose homeostasis

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240125060804N1**

Registration date: **2024-01-31, 1402/11/11**

Registration timing: **prospective**

Last update: **2024-01-31, 1402/11/11**

Update count: **0**

##### Registration date

2024-01-31, 1402/11/11

##### Registrant information

###### Name

Mostafa Vaghari-Tabari

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 3223 2963

###### Email address

vagharim@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-19, 1402/11/30

##### Expected recruitment end date

2024-07-21, 1403/04/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigating the effect of zinc supplementation on the levels of oxidative stress and inflammation markers and glucose homeostasis in overweight or obese patients with metabolic syndrome

## Public title

Investigating the effects of zinc in reducing the risk of diabetes and cardiovascular diseases

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age over 18 to 70 years old Definite diagnosis of metabolic syndrome based on clinical symptoms and laboratory findings. Overweight or obesity (BMI above 25) Obtaining written informed consent from patients

### Exclusion criteria:

Taking zinc supplements at least three months before starting the study The need to take blood sugar and lipid lowering drugs according to the doctor's opinion History of other diseases related to oxidative stress and inflammation such as cardiovascular diseases, autoimmune diseases, types of diabetes, IBD, asthma, cancer, kidney and liver diseases, Infectious diseases Smoking and alcohol consumption

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

At the beginning of the study, after applying the inclusion and exclusion criteria, patients will be divided into two groups to receive zinc supplements (30 patients) and placebo (30 patients). Randomization will be done using a computer-generated random number table.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Blinding of the clinical researcher and patients will be done. The zinc supplement and placebo will be delivered to the clinical researcher with identical appearance.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Research Ethics Committees of Islamic Azad University, Shahrood Branch

#### Street address

Islamic Azad University, Shahrood branch, University blvd

#### City

Shahrood

#### Province

Semnan

#### Postal code

43189-36199

#### Approval date

2024-01-13, 1402/10/23

#### Ethics committee reference number

IR.IAU.SHAHROOD.REC.1402.072

## 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

Serum insulin

### Timepoint

Before the intervention, after the end of the intervention period

### Method of measurement

Commercial ELISA kit

## 2

### Description

Serum MDA

### Timepoint

Before the intervention, after the end of the intervention period

### Method of measurement

TBARS method

## 3

### Description

Serum zinc

### Timepoint

Before the intervention, after the end of the intervention period

### Method of measurement

Commercial spectrophotometry kit

#### 4

**Description**

Serum total antioxidant capacity

**Timepoint**

Before the intervention, after the end of the intervention period

**Method of measurement**

FRAP method

#### 5

**Description**

Serum lipid profile

**Timepoint**

Before the intervention, after the end of the intervention period

**Method of measurement**

Commercial spectrophotometry kit

#### 6

**Description**

Serum CRP

**Timepoint**

Before the intervention, after the end of the intervention period

**Method of measurement**

Commercial kit

#### 7

**Description**

Serum TNF- $\alpha$

**Timepoint**

Before the intervention, after the end of the intervention period

**Method of measurement**

Commercial ELISA kit

#### 8

**Description**

HbA1C levels

**Timepoint**

Before the intervention, after the end of the intervention period

**Method of measurement**

Commercial kit

#### 9

**Description**

Serum fasting glucose

**Timepoint**

Before the intervention, after the end of the intervention period

**Method of measurement**

Commercial kit

#### 10

**Description**

Body Mass Index

**Timepoint**

Before the intervention, after the end of the intervention period

**Method of measurement**

Scales, meter

#### 11

**Description**

Waist circumference

**Timepoint**

Before the intervention, after the end of the intervention period

**Method of measurement**

Meter

### Secondary outcomes

empty

### Intervention groups

#### 1

**Description**

Intervention group: Patients with metabolic syndrome receiving zinc supplementation. The dose of zinc received will be 30 mg orally once a day. Supplementation will be done for 12 weeks.

**Category**

Prevention

#### 2

**Description**

Control group: Patients with metabolic syndrome receiving placebo. The placebo will be starch tablets, similar in appearance to zinc tablets, and will be taken once a day for 12 weeks.

**Category**

Placebo

### Recruitment centers

#### 1

**Recruitment center****Name of recruitment center**

Dr. Shakri's endocrinology clinic

**Full name of responsible person**

Habibeh Sadat Shakeri

**Street address**

1st Floor, Doctors Building, Dr. Hekmati Alley, South Shariati St.

**City**

بجنورد

**Province**

North Khorasan

**Postal code**

9414864157

**Phone**

+98 58 3222 6606

**Email**  
drhssh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Behrooz yahyaee

**Street address**

Islamic Azad University, Shahrood branch, University  
blvd

**City**

Shahrud

**Province**

Semnan

**Postal code**

43189-36199

**Phone**

+98 23 3239 1890

**Email**

behroozyahyaee@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Islamic Azad University

**Proportion provided by this source**

100

**Public or private sector**

Private

**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**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mostafa Vaghari-Tabari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

**Street address**

At the end of Modares Alley, Jamal Alley, Keshavarz  
Street

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**Postal code**

4717975666

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+98 11 3223 2963

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**Email**

vagharim@tbzmed.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Mostafa Vaghari-Tabari

**Position**

Assistant Professor

**Latest degree**

Ph.D.

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## Person responsible for updating data

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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 information related to the study can be shared

### **When the data will become available and for how long**

Access starts six months after the results are published.

### **To whom data/document is available**

Researchers working in academic and scientific institutions

### **Under which criteria data/document could be used**

Access to the data will be given to people working in scientific and academic institutions only by citing scientific reasons, and all statistical analyzes on the data will be allowed.

### **From where data/document is obtainable**

To receive the data, contact Mostafa Vaghari- Tabari via email mostafavaghari@yahoo.com or vagharim@tbzmed.ac.ir

### **What processes are involved for a request to access data/document**

After correspondence with the responsible person, the scientific reasons for the data request will be discussed with all members of the research team, and if the reasons are scientific and there is no legal prohibition, the data will reach the requester within a week.

### **Comments**