

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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- α

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

behroozyahyaei@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

City

Babol

Province

Mazandaran

Postal code

4717975666

Phone

+98 11 3223 2963

Fax

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.

Other areas of specialty/work

Biochemistry

Street address

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

City

Babol

Province

Mazandaran

Postal code

4717975666

Phone

+98 11 3223 2963

Fax

Email

vagharim@tbzmed.ac.ir

Person responsible for updating data

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

City

Babol

Province

Mazandaran

Postal code

4717975666

Phone

+98 11 3223 2963

Fax

Email

vagharim@tbzmed.ac.ir

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