

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jun 2026

### Study of oral zinc supplementation effect on the superoxide dismutase gene expression and enzyme activity, and oxidative stress index in overweight type 2 diabetic patients.

#### Protocol summary

##### Study aim

Determine the oral zinc supplementation effect on superoxide dismutase gene expression and enzyme activity, stress-oxidative index, in type 2 diabetic patients.

##### Design

double blind clinical trial, phase III, on 70 type 2 diabetic patients. Participants will be randomly divided to two groups, intervention(35) and control(35).

##### Settings and conduct

patient with type 2 diabetes, who referred to Diabetes and Metabolic Diseases Clinic of Endocrinology and Metabolism Research Institute. 7 mL blood samples will be taken from each participant after 12 hour fasting condition. In other words, we will allocate 2ml blood in EDTA tube for gene analysis and HbA1c assay, and 5ml in plain tube for biochemistry assays. Biochemical data will be evaluated and reported before and after the 8 weeks of supplementation for all patients at the end of study. In this study, all the participants, the primary researcher, health care providers, sample collectors, and those who prepare manuscript draft were blinded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: male/female with age 40-65, type 2 diabetes, Exclusion criteria: cigarette smoking, cancer, thyroid or gastrointestinal or renal disorders, antibiotics and vitamin.

##### Intervention groups

The case groups will take 25 mg the gluconate Zinc capsule (twice daily), and the control group will take Avicel capsule twice daily.

##### Main outcome variables

Superoxide dismutase gene expression, superoxide dismutase activity, Zinc, Fasting Blood Sugar, Hemoglobin A1c, Nitrotyrosine, Total antioxidant capacity, Total oxidant capacity, Malondialdehyde, Insulin, Body mass index

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150831023838N1**

Registration date: **2018-01-05, 1396/10/15**

Registration timing: **prospective**

Last update: **2018-03-25, 1397/01/05**

Update count: **1**

##### Registration date

2018-01-05, 1396/10/15

##### Registrant information

##### Name

Mohammad Reza Nazem

##### Name of organization / entity

Tarbiat Modares University

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8851 2592

##### Email address

mohammadreza.nazem@modares.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-01-06, 1396/10/16

##### Expected recruitment end date

2018-03-21, 1397/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Study of oral zinc supplementation effect on the superoxide dismutase gene expression and enzyme activity, and oxidative stress index in overweight type 2 diabetic patients.

### Public title

Study of oral zinc supplementation effect on type 2 diabetes

### Purpose

Basic science

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Afflicted with type 2 diabetes mellitus BMI= 25-30 kg/m<sup>2</sup>  
HbA1c ≥7

#### Exclusion criteria:

Smoking Taking diuretics Taking antibiotics Taking multivitamins containing zinc Gastrointestinal disorders Thyroid disorders Cancer history Renal disorders Liver disorders

### Age

From **40 years** old to **65 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple-block randomization

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this study, all the participants, the primary researcher, health care providers, sample collectors, and those who prepare manuscript draft were blinded.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

Ethics committee

### Name of ethics committee

Research Ethics Committee of Endocrinology  
Metabolism Research institute, Tehran University of  
Medic

### Street address

Tehran University of Medical sciences, Endocrinology  
Metabolism Research institute, jalal al ahmad Ave,  
Iran

### City

Tehran

### Province

Tehran

### Postal code

1411713137

### Approval date

2016-03-02, 1394/12/12

### Ethics committee reference number

IR.TUMS.EMRI.REC.1395.00105

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes mellitus

#### ICD-10 code

E11

#### ICD-10 code description

Type 2 diabetes mellitus

## Primary outcomes

### 1

#### Description

Gene expression of Superoxide dismutase

#### Timepoint

Before and 8 weeks after intervention

#### Method of measurement

Real time PCR

### 2

#### Description

Superoxide dismutase activity

#### Timepoint

Before and 8 weeks after intervention

#### Method of measurement

ELISA

### 3

#### Description

Serum levels of Zinc

#### Timepoint

Before and 8 weeks after intervention

#### Method of measurement

Atomic Absorption Spectroscopy

### 4

Description

Serum levels of Malondialdehyde  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
ELISA

**5**  
**Description**  
Serum levels of Total Antioxidant Capacity  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
ELISA

**6**  
**Description**  
Serum levels of Total Oxidant Capacity  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
ELISA

**7**  
**Description**  
Serum levels of Nitrotyrosine  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
ELISA

**8**  
**Description**  
Serum levels of Fasting Blood Sugar  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
spectroscopy

**9**  
**Description**  
Glycated hemoglobin  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
High Efficiency Liquid Chromatography (HPLC)

**10**  
**Description**  
Serum levels of Cholesterol  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
spectroscopy

**11**  
**Description**  
Serum levels of Triglycerid

**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
spectroscopy

**12**  
**Description**  
Serum levels of Insulin  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
Electrochemiluminescence

**13**  
**Description**  
Height  
**Timepoint**  
Before the intervention  
**Method of measurement**  
Meter

**14**  
**Description**  
Weight  
**Timepoint**  
Before and 8 weeks after intervention  
**Method of measurement**  
Scales

**Secondary outcomes**  
empty

**Intervention groups**

**1**  
**Description**  
Intervention group: One day will take, 2 capsules of zinc gluconate 25 mg for 60 days. These capsules are made by ALHAVI Company in Iran.

**Category**  
Treatment - Drugs

**2**  
**Description**  
Control group: One day will take, 2 capsules of Avesil , for 60 days. These capsules are made by ALHAVI Company in Iran.

**Category**  
Placebo

**Recruitment centers**

**1**  
**Recruitment center**  
**Name of recruitment center**  
Diabetes & Metabolic Diseases Clinic of Endocrinology

and Metabolism Research Institute  
**Full name of responsible person**  
Mojgan Asadi  
**Street address**  
No. 4, North Karegar Ave., shahrivar St.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
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**Phone**  
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**Email**  
asadim@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Endocrinology and metabolism research institute  
**Full name of responsible person**  
Dr. Neda Mehrdad  
**Street address**  
Tehran University of Medical sciences, Endocrinology  
Metabolism Research institute, jalal al ahmad Ave,  
Tehran, Iran.  
**City**  
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**Postal code**  
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**Email**  
nmehrdad@Tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Endocrinology and metabolism research institute

#### Proportion provided by this source

63

#### 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

### 2

#### Sponsor

**Name of organization / entity**

Tarbiat Modares university faculty of medical sciences  
**Full name of responsible person**  
Dr. Mansoureh Movahedin  
**Street address**  
Tarbiat Modares university, Jalal AleAhmad Nasr Ave,  
Tehran, Iran.  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
111-14115  
**Phone**  
+98 21 8288 3108  
**Email**  
pres@modares.ac.ir  
**Web page address**  
<http://www.modares.ac.ir>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tarbiat Modares university faculty of medical sciences

#### Proportion provided by this source

30

#### 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

Tehran University of Medical Sciences

#### Full name of responsible person

Mojgan Asadi

#### Position

Associate Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

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#### Email

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tarbiat Modares University, Faculty of Medical Sciences

**Full name of responsible person**

Mohammadrezanazem

**Position**

Ph.D. student of Clinical Biochemistry

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

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Tarbiat Modares university, Jalal AleAhmad Nasr Ave, Tehran, Iran.

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Mohammadreza.nazem@modares.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tarbiat Modares university

**Full name of responsible person**

Mohammad reza nazem

**Position**

Ph.D Student

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

**Street address**

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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**

Article

**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