

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)

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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/m²
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.
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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.
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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
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Tarbiat Modares university, Jalal AleAhmad Nasr Ave,
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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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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tarbiat Modares University, Faculty of Medical Sciences

Full name of responsible person

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Position

Ph.D. student of Clinical Biochemistry

Latest degree

Master

Other areas of specialty/work

Biochemistry

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Person responsible for updating data

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Latest degree

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Other areas of specialty/work

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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