Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 scienece

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

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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 expresion 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 Suger
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 Cgromotography (HPLC)

10

Description
Serum levels of Cholestrol
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, Tehran, Iran.

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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

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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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Person responsible for updating data

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Other areas of specialty/work
Biochemistry

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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