

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Zinc and Selenium co-supplementations on blood glucose and inflammatory/antioxidant biomarkers in Type 2 Diabetes Mellitus patients

Protocol summary

Study aim

Determination of effect of Zinc and Selenium co-supplementations on blood glucose and inflammatory/antioxidant biomarkers in Type 2 Diabetes Mellitus patients

Design

Randomized double blind study with control group and parallel groups

Settings and conduct

This study will be held in Ghaem Hospital. Sample size is 80 and subjects will be distribute in each of 4 groups randomly. participants and investigators are blind.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Type 2 Diabetes, 18.5 < Body Mass Index < 30, 18 < Age < 60, 7 < Hemoglobin A1c < 9
Exclusion Criteria: Haven't consumed zinc and selenium supplements in last 3 month; Diabetes complications; Autoimmune disorders; Cancer; Participate in any other studies; Pregnancy; Lactating; Smoking

Intervention groups

in this study participants will distribute in 4 groups and each group have 20 individuals. Intervention group 1: Supplement Zinc+ Supplement Selenium Intervention group 2: Supplement Zinc+ placebo Selenium Intervention group 3: placebo Zinc+ supplement Selenium Control group 4: Placebo Zinc+ Placebo Selenium

Main outcome variables

Fasting Blood Glucose; Insulin; Hemoglobin A1c; Interleukin 1 beta; Super Oxid Dismutase; Glutathione Peroxidase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190407043194N1**

Registration date: **2019-08-14, 1398/05/23**

Registration timing: **retrospective**

Last update: **2019-08-14, 1398/05/23**

Update count: **0**

Registration date

2019-08-14, 1398/05/23

Registrant information

Name

Maryam khosravi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3800 2103

Email address

khosravim@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-07-21, 1398/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Zinc and Selenium co-supplementations on blood glucose and inflammatory/antioxidant biomarkers in Type 2 Diabetes Mellitus patients

Public title

The effect of Zinc and Selenium co-supplementation in T2D patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 Diabetes Melitus 7 < HA1c < 9 18.5 < BMI < 30
18 < Age < 65

Exclusion criteria:

Zinc and Selenium consumption in last 3 month Diabetes complications autoimmune disorders cancer participating in any other studies pregnancy Lactating Smoking

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will allocate in each group by: Block Sampling, individual, Stratified Randomization, tools used: Computer Software.

Blinding (investigator's opinion)

Double blinded

Blinding description

in this study investigator and participants are blind from groups and how they are randomized

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Mashhad University of Medical Sciences, University campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2019-03-13, 1397/12/22

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.736

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Hemoglobin A1c

Timepoint

Before and after study

Method of measurement

Laboratory test

2

Description

FBS

Timepoint

Before and after of intervention

Method of measurement

Laboratory test

3

Description

Insulin

Timepoint

Before and after intervention

Method of measurement

Laboratory test

4

Description

Interleukin 1 beta

Timepoint

Before and after intervention

Method of measurement

Laboratory test

5

Description

Superoxide Dismutase

Timepoint

Before and after intervention

Method of measurement

Laboratory test

6**Description**

Glutathione peroxidase

Timepoint

Before and after intervention

Method of measurement

Laboratory test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention Group 1: Zinc Supplement (contains 25mg zinc gluconate, Produced in Dine pharmacy Company, 1 time per day for 2 months, consume with water) and Selenium Supplement (Contains 100 mcg sodium selenite, produced in School of pharmacy's MUMS, 1 time per day for 2 months, consume with water).

Category

Treatment - Drugs

2**Description**

Control group: Receive 1 Zinc Placebo tab (Produced in Dine Pharmacy company) and 1 Selenium placebo tab (Produced in school of Pharmacy at Mashhad University of Medical Sciences)

Category

Placebo

3**Description**

Intervention group 2: Zinc Supplement (contains 25mg zinc gluconate, Produced in Dine pharmacy Company, 1 time per day for 2 months, consume with water) and Selenium Placebo (Produced in School of pharmacy's MUMS, 1 time per day for 2 months, consume with water).

Category

Treatment - Drugs

4**Description**

Intervention group 3: Intervention Group 1: Zinc Placebo (Produced in Dine pharmacy Company, 1 time per day for 2 months, consume with water) and Selenium Supplement (Contains 100 mcg sodium selenite, produced in School of pharmacy's MUMS, 1 time per day for 2 months, consume with water).

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ghaem Hospital's Clinic

Full name of responsible person

Mariam Khosravi

Street address

Ghaem Hospital's Clinic, Parastar Ave, Ahmad_Abad ST

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2367

Fax

+98 51 3800 2421

Email

khosravim@mums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Saeid Eslami

Street address

Mashhad University of Medical Sciences, University campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Phone

+98 51 3800 2103

Fax

+98 51 3800 2421

Email

ESLAMIS@MUMS.AC.IR

Grant name

Priority Projects

Grant code / Reference number**Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

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

+98 51 3800 2367
Fax
+98 51 3800 2421
Email
khosravim@mums.ac.ir

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamed Khedmatgozar
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Nutrition Department, medicine School, Mashhad
University of Medical Sciences, University campus,
Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3800 2367
Fax
+98 51 3800 2421
Email
khedmatgozarh961@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mariam Khosravi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrotrion, medicine school, Mashhad
University of Medical Sciences, University campus,
Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Hamed Khedmatgozar
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Nutrition Department, Medicine School, Mashhad
University of Medical Sciences, University campus,
Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 513802367
Email
Khedmatgozarh961@mums.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

Primary outcomes will be share.

When the data will become available and for how long

Starting 6 month after publication

To whom data/document is available

Researchers

Under which criteria data/document could be used

For Metanalysis

From where data/document is obtainable

Making contact with Dr. Mariam Khosravi

What processes are involved for a request to access

data/document

Making contact with Dr. Mariam Khosravi and asking for the data, if she approved, request will be send to

university president, if they approved the data will send for applicant.

Comments