

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effects of selenium on oxidative stress and glycemic control of type 2 diabetes

Protocol summary

Summary

The objective of this double blind placebo-controlled trial is to investigate the effects of selenium on oxidative stress and glycemic control of type 2 diabetes. Sixty patients with type 2 diabetes who meet the eligibility criteria will be recruited and after signing the informed consent assigned randomly (block randomization) to receive selenium (200 micg/d) or placebo for 12 weeks. HgA1c, FBS, fasting plasma insulin level, plasma selenium level, lipid profil, and oxidative stress level at the baseline and the end of the study period. Compliance (pill counting) and patient's general condition are evaluated at the 6th week of the study. Insulin resistance will be measured by HOMA-IR method and oxidative stress will be measured by lipid oxidation via TBARS method and antioxidant capacity via FRAP method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138901203667N1**

Registration date: **2010-02-20, 1388/12/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-02-20, 1388/12/01

Registrant information

Name

Mania Radfar

Name of organization / entity

TUMS

Country

Iran (Islamic Republic of)

Phone

+98 21 6695 4709

Email address

radfarma@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vive-chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2010-02-20, 1388/12/01

Expected recruitment end date

2010-11-22, 1389/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of selenium on oxidative stress and glycemic control of type 2 diabetes

Public title

Effects of selenium on oxidative stress and glycemic control of type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 18-70 years, FPG<250mg/dL & HgA1c <9%, not using insulin during past 8 weeks, signing the informed consent Exclusion criteria: taking selenium supplements during the past 6 months, renal dysfunction (GFR less than 50ml/min), hepatic dysfunction (ALT, AST more than 3xULN), pregnancy, lactation, type 1 diabetes

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-chancellor for research, Tehran University of Medical Sciences

Street address

Central organization of Tehran University of Medical Sciences, Ghods avenue, Keshavarz Blvd, Tehran,

City

Tehran

Postal code

Approval date

2009-01-26, 1387/11/07

Ethics committee reference number

7709-33-03-87

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E10, E14

ICD-10 code description

Diabetes Mellitus

Primary outcomes

1

Description

controlling blood glucose

Timepoint

12 weeks

Method of measurement

A1c, FBG

2

Description

oxidative stress

Timepoint

12 weeks

Method of measurement

FRAP, TBARS

Secondary outcomes

1

Description

Lipid profile

Timepoint

12 weeks

Method of measurement

Total cholesterol, LDL, HDL, TG

2

Description

Inulin resistance

Timepoint

12 weeks

Method of measurement

HOMA-IR

Intervention groups

1

Description

200 microgram selenium daily for 12 weeks

Category

Treatment - Drugs

2

Description

one placebo capsule daily for 12 weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrinology and metabolism research center

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Saeidi

Street address

central organization of Tehran University of Medical Sciences, Ghods avenue, Keshavrz Blvd.

City

Tehran

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

Yes

Title of funding source

Vice-chancellor for Research, Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Dr Mania Radfar

Position

Assistant professor

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty