

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of supplementation with organic selenium on peripheral neuropathy and biochemical markers in people with melitus diabetes: A parallel randomized controlled clinical trial

Protocol summary

Study aim

Evaluating the effect of supplementation with organic selenium on peripheral neuropathy and biochemical markers in people with diabetes

Design

This is a phase 3, triple blind randomized controlled clinical trial with a parallel design in which the target population is 50 eligible patients with peripheral diabetic neuropathy. Computer software (RAS: Random Allocation Software) will be used to randomize.

Settings and conduct

Sampling will be done in Nutrition Research Center. After the approval of the Ethics Committee and the registration of the trial in IRCT, the researcher will express the objectives of the study to the participants and obtain a form of informed consent. After completing the questionnaires, each person will be given 60 number of 500 mg identical capsules for bio-monthly use. monitoring will be blunt. Participants, researchers, analyst, and the safety and data monitoring committee will be blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women or men aged 40-70 years, type 2 diabetes based on the diagnosis of endocrinologist, peripheral diabetic neuropathy based on Michigan neuropathy screening tool. Exclusion criteria: Peripheral neuropathy due to other diseases, other chronic diseases, pregnancy, breastfeeding.

Intervention groups

Participants will be allocated into one of two groups of organic selenium or placebo by an allocation ratio of 1: 1. They will take a daily 500 mg capsule containing 200 micrograms of selenium or placebo.

Main outcome variables

Symptoms of neuropathy; Severity of neuropathy; Serum levels of glycemic markers; Serum indicator of Pro-oxidant Antioxidant Balance (PAB)

General information

Reason for update

Under the above request and approval by the Center Council and Ethics Committee, the 4 study groups should be reduced to two groups: organic selenium and placebo, and the sample size should be reduced from 100 people in 4 groups to 50 people in 2 groups. Please agree.

Acronym

IRCT registration information

IRCT registration number: **IRCT20131009014957N10**

Registration date: **2020-08-03, 1399/05/13**

Registration timing: **prospective**

Last update: **2025-03-08, 1403/12/18**

Update count: **1**

Registration date

2020-08-03, 1399/05/13

Registrant information

Name

Azizeh Farshbaf-khalili

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1333 9151

Email address

farshbafa@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2022-01-21, 1400/11/01

Actual recruitment start date

2021-04-21, 1400/02/01

Actual recruitment end date

2024-10-22, 1403/08/01

Trial completion date

2024-10-22, 1403/08/01

Scientific title

The effect of supplementation with organic selenium on peripheral neuropathy and biochemical markers in people with melitus diabetes: A parallel randomized controlled clinical trial

Public title

The effect of supplementation with organic selenium on peripheral neuropathy and biochemical markers in people with melitus diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women or men aged 40-70 years Type 2 Diabetes based on the diagnosis of endocrinologist Diabetic peripheral neuropathy based on Michigan neuropathy screening tool

Exclusion criteria:

Peripheral neuropathy due to other diseases (including alcohol consumption, chemotherapy, congenital disease, chronic inflammation, thyroid disorders, vitamin B12 deficiency, HIV, and idiopathic peripheral neuropathy) Other chronic diseases such as cancer, chronic renal failure, CVA, Parkinson, Alzheimer Increased risk of bleeding due to coagulation disorders Selenium or vitamin E supplementation during last 3 months Pregnancy Breastfeeding

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be allocated into one of the two groups of organic selenium or placebo using computer software (RAS: Random Allocation Software) by four and 8 blocks with a 1:1 allocation ratio. Random allocation sequences will be generated by the non-involved person in the research. The flacons will be numbered from 1 to 50 based on the sequence produced.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Each person will be given a 60-capsule mattee and enclosed flacons consisting of identical main medications or placebos for bi-monthly use that will be provided at the Nutrition Research Center. They will receive 500 mg capsules once a day containing 200 micrograms of selenium or placebo. All capsules will be identical, and all participants, researchers (who will also be evaluators of the outcomes), health care providers, and the Data Safety and Monitoring Committee will be blind.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Nutrition Research Center, Tabriz University of Medical Sciences; Attar Neishabouri avenue, Golgasht

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2020-06-29, 1399/04/09

Ethics committee reference number

IR.TBZMED.REC.1399.322

Health conditions studied**1****Description of health condition studied**

Diabetic peripheral neuropathy

ICD-10 code

G63*

ICD-10 code description

Polyneuropathy in diseases classified elsewhere

Primary outcomes**1****Description**

Neuropathy symptoms

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

Michigan neuropathy screening tool

2

Description

Neuropathy severity

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

Toronto Clinical Scoring System

3

Description

Serum levels of glycemic markers (fasting blood sugar, insulin resistance, blood sugar monitored by the individual)

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

Biochemical methods and glucometer

4

Description

Pro-oxidant antioxidant balance

Timepoint

Pro-oxidant antioxidant balance

Method of measurement

Biochemical method

Secondary outcomes

1

Description

Quality of life score

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

World Health Organization quality of life assessment instrument (WHOQOL -BREF)

2

Description

Depression score

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Beck Depression Inventory-2

3

Description

Sleep quality score

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Pittsburgh Sleep Quality Questionnaire

4

Description

Sexual satisfaction score

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Larson's sexual satisfaction questionnaire (LSSQ)

5

Description

Side effects

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Questionnaire

6

Description

Satisfaction with medication

Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Satisfaction rate questionnaire

Intervention groups

1

Description

Intervention group 1: Organic selenium group. They will take one 500 mg oral capsule containing 200 micrograms of selenium daily for 8 weeks. Organic selenium will be produced by the yeast *Saccharomyces cerevisiae* from sodium selenite. The rest of the capsule space will be filled with yeast powder. Organic selenium will be produced at the Nutrition Research Center.

Category

Treatment - Drugs

2

Description

Control group: Placebo group. They will take one 500 mg capsule containing starch daily for 8 weeks. The placebo capsules will be provided at the Nutrition Research Center.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Nutrition Research Center

Full name of responsible person

Azizeh Farshbaf-Khalili

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Medical Sciences; Attar Neyshabouri avenue, Golgasht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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<https://researchvice.tbzmed.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Azizeh Farshbaf-khalili

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Majid Mobasseri

Position

Professor

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Subspecialist

Other areas of specialty/work

Others

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Person responsible for updating data

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available

Title and more details about the data/document

Part of the outcome data will be published

**When the data will become available and for how
long**

6 months after printing the results

To whom data/document is available

Researchers at institutions have access to data

Under which criteria data/document could be used

In order to help scientific progress in the field of research

From where data/document is obtainable

farshbafa@tbzmed.ac.ir

**What processes are involved for a request to access
data/document**

Scientific approval of applicant by Tabriz University of
Medical Sciences

Comments