Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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
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Iran (Islamic Republic of)
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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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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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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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Professor

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Others

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Person responsible for updating data

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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