

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Investigation of the effect of high-dose vitamin D3 with alpha linoleic acid (flaxseed oil) supplementation on serum indices of inflammation and oxidative stress in the elderly with type 2 diabetes.

#### Protocol summary

##### Study aim

Investigation of the effect of high-dose vitamin D3 with alpha-linoleic acid (flaxseed oil) supplementation on serum indices of inflammation and oxidative stress in the elderly with type 2 diabetes.

##### Design

A double blinded randomized controlled clinical trial with parallel groups

##### Settings and conduct

This study will be a randomized, double-blind clinical trial in type 2 diabetes patients in Emam Reza hospital in Tabriz. Participants will be recruited through a convenience sampling and randomly divided into two groups matched based on body mass index, age. Similar envelopes will be used to conceal the allocation in opaque numbered packages.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: the age of 65 and above the patient has been diagnosed with type 2 diabetes based on medical records hemoglobin A1C level is between 10-5/6 anti-diabetic treatment, which has not been changed for at least 8 weeks 25-hydroxy vitamin D3 level between 125-30 nano moles per liter Exclusion criteria: Type 1 diabetes Smoking and alcohol consumption Severe uncontrolled diabetes Severe uncontrolled blood pressure Lack of interest in continuing the study Unusual stress event during the study 25-hydroxy vitamin D3 level less than 30 and higher than 125 nano moles per liter

##### Intervention groups

Intervention group: vitamin D3 supplements at 50,000 IU per week and 1000 mg of flaxseed oil soft gel(made by Barij esans company) three times a day for 8 weeks. Control group: flaxseed oil soft gel placebo three times a day and a vitamin D3 placebo once weekly for 8 weeks

##### Main outcome variables

Serum concentration of inflammatory indices (hs-CRP),

Serum concentration of oxidative stress indices (MDA and TAC)

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161022030424N8**

Registration date: **2023-09-12, 1402/06/21**

Registration timing: **prospective**

Last update: **2023-09-12, 1402/06/21**

Update count: **0**

##### Registration date

2023-09-12, 1402/06/21

##### Registrant information

##### Name

Neda Dolatkhan

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3336 1928

##### Email address

dolatkhan@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-09-23, 1402/07/01

##### Expected recruitment end date

2025-01-19, 1403/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Investigation of the effect of high-dose vitamin D3 with alpha linoleic acid (flaxseed oil) supplementation on serum indices of inflammation and oxidative stress in the elderly with type 2 diabetes.

**Public title**  
vitamin D3 and flaxseed oil supplementation effects in type 2 diabetes

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
the age of 65 and above the patient has been diagnosed with type 2 diabetes based on medical records hemoglobin A1C level is between 10-5/6 anti-diabetic treatment, which has not been changed for at least 8 weeks 25-hydroxy vitamin D3 level between 125-30 nano moles per liter  
**Exclusion criteria:**  
Type 1 diabetes Smoking and alcohol consumption Severe uncontrolled diabetes Severe uncontrolled blood pressure Lack of interest in continuing the study Unusual stress event during the study 25-hydroxy vitamin D3 level less than 30 and higher than 125 nano moles per liter

**Age**  
From **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**  
Target sample size: **104**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
A block randomization method will be used to allocate participants to the groups with a 1:1 allocation using random allocation software (RAS) with block sizes of 2 and 4. Similarly sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
Intervention and placebo supplements will be prepared in exactly the same way in terms of shape, color, and odor, and will be placed in a small envelope containing 8 and 168 tablets for each participant for 8 weeks consumption. The envelopes will be opened in the order in which the participants enter this stage from number 1, and an envelope containing the supplement will be

provided to the participant for 8 weeks. Outcome assessors, the person responsible for statistical analysis of the data, and the respondents will be blinded to the type of supplement received until the end of the study.

**Placebo**  
Used

**Assignment**  
Parallel

**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

Research Vice Chancellor, Tabriz University of Medical Sciences, Daneshgah Ave.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5165665931

#### Approval date

2023-06-12, 1402/03/22

#### Ethics committee reference number

IR.TBZMED.REC.1402.210

## 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

Serum concentration of inflammatory indices (hs-CRP)

#### Timepoint

Measurement of the serum levels of inflammatory markers at baseline (before intervention) and 8 weeks after vitamin D3 with alpha - linoleic acid (flaxseed oil) supplementation

#### Method of measurement

Biochemical analysis

## 2

### **Description**

Serum concentration of oxidative stress indices (MDA and TAC)

### **Timepoint**

Measurement of the serum levels of inflammatory markers at baseline (before intervention) and 8 weeks after vitamin D3 with alpha - linoleic acid (flaxseed oil) supplementation

### **Method of measurement**

Biochemical analysis

## **Secondary outcomes**

### 1

#### **Description**

Anthropometric indices

#### **Timepoint**

Measurement of the anthropometric indices at baseline (before intervention) and 8 weeks after vitamin D3 with alpha - linoleic acid (flaxseed oil) supplementation

#### **Method of measurement**

Seca digital scale

### 2

#### **Description**

Quality of life

#### **Timepoint**

Evaluation of the quality of life at baseline (before intervention) and 8 weeks after vitamin D3 with alpha - linoleic acid (flaxseed oil) supplementation

#### **Method of measurement**

SF-36 quality of life questionnaire

### 3

#### **Description**

Metabolic indices(triglycerides, LDL cholesterol)

#### **Timepoint**

Measurement of Metabolic indices(triglycerides, LDL cholesterol) at baseline (before intervention) and 8 weeks after vitamin D3 with alpha - linoleic acid (flaxseed oil) supplementation

#### **Method of measurement**

Biochemical analysis

## **Intervention groups**

### 1

#### **Description**

Intervention group: vitamin D3 supplements at 50,000 IU per week and 1000 mg of flaxseed oil soft gel(made by Barij esans company) three times a day for 8 weeks

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: flaxseed oil soft gel placebo three times a day and a vitamin D3 placebo once weekly for 8 weeks

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Emam Reza hospital

##### **Full name of responsible person**

Neda Dolatkah

##### **Street address**

Emam Emam Reza hospital, Golgasht Str., Azadi Ave., Tabriz

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5163995479

##### **Phone**

+98 41 3336 1928

##### **Email**

dolatkahn@tbzmed.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Parviz Shahabi

##### **Street address**

Research Vice Chancellor, No. 2 Central Building, Tabriz University of Medical Sciences, Golgasht Str.

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##### **Email**

shahabip@tbzmed.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

No

#### **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**  
Neda Dolatkah  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
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Nutrition  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

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

### Study Protocol

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

### Statistical Analysis Plan

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

### Informed Consent Form

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

### Clinical Study Report

Undecided - It is not yet known if there will be 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