Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 Dolatkhah

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3336 1928

Email address
dolatkhahn@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 2and 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 Dolatkhah
Street address
Emam Emam Reza hospital, Golgasht Str., Azadi Ave., Tabriz
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Tabriz
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dolatkhahn@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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+98 41 3335 7310
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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 Dolatkhah

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

Neda Dolatkhah

Position

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Neda Dolatkhah

Position

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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