

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Investigation of the effect of Curcumin and/or omega-3 polyunsaturated fatty acids supplementation on anthropometric indices, glucose hemostasis, markers of cardiometabolic risk and gene expression of vascular endothelial growth factor and serum concentrations of inflammatory and oxidative stress indices in type 2 diabetic patients

#### Protocol summary

##### Study aim

Determining of the effect of Curcumin and/or omega-3 polyunsaturated fatty acids supplementation on anthropometric indices, glucose hemostasis, markers of cardiometabolic risk and gene expression of vascular endothelial growth factor and serum concentrations of inflammatory and oxidative stress indices in type 2 diabetic patients

##### Design

A triple blinded randomized controlled clinical trial with parallel groups

##### Settings and conduct

This study will be a randomized, triple-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 four groups matched based on body mass index, dosage and type of drug. Similar envelopes will be used to conceal the allocation in opaque numbered packages.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: > 18 years old, diagnosed as having T2DM based on the criterion of the American Diabetes Association, at least moderately controlled diabetes ( $\%5/8 > \text{HbA1c}$ ) and a stable anti-diabetic drug regimen (over 4 months) before starting the study Exclusion criteria: Omega 3 fatty acids supplement intake, multivitamin-mineral supplements or medicinal products that interfere with patients' lipid profile, cancer and any chronic disease other than diabetes, pregnancy and lactation

##### Intervention groups

Intervention group 1: Two 1000 mg omega-3 capsules daily and two 500 mg turmeric capsules for 12 weeks.  
Intervention group 2: Two 500 mg turmeric capsules and

two placebo capsules of Omega 3 containing sunflower oil Intervention group 3: Two 1000 mg omega-3 capsules and 2 capsules of turmeric placebo Intervention group 4 (control): two placebo omega-3 capsules and 2 capsules of turmeric placebo

##### Main outcome variables

Anthropometric indices, glucose homeostasis, cardiometabolic risk markers and vascular endothelial growth factor gene expression

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20161022030424N5**

Registration date: **2019-12-02, 1398/09/11**

Registration timing: **prospective**

Last update: **2019-12-02, 1398/09/11**

Update count: **0**

##### Registration date

2019-12-02, 1398/09/11

##### 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**

2019-12-22, 1398/10/01

**Expected recruitment end date**

2020-08-22, 1399/06/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Investigation of the effect of Curcumin and/or omega-3 polyunsaturated fatty acids supplementation on anthropometric indices, glucose hemostasis, markers of cardiometabolic risk and gene expression of vascular endothelial growth factor and serum concentrations of inflammatory and oxidative stress indices in type 2 diabetic patients

**Public title**

Curcumin and/or omega-3 polyunsaturated fatty acids supplementation in diabetes mellitus

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

> 18 years old Diagnosed as having T2DM based on the criterion of the American Diabetes Association At least moderately controlled diabetes ( $HbA1c > 5.8$ ) A stable anti-diabetic drug regimen (over 4 months) before starting the study

**Exclusion criteria:**

Omega 3 fatty acids supplement intake Multivitamin-mineral supplements or medicinal products that interfere with patients' lipid profile Cancer and any chronic disease other than diabetes Pregnancy and lactation Smoking Drinking

**Age**

From 18 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: 100

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

A block randomization method will be used to allocate participants to the groups with a 1:1:1:1 allocation using

random allocation software (RAS) with block sizes of 4 and 8. Similar sealed envelopes will be used to conceal the allocation in a sequentially numbered opaque package.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The clinical trial will be triple-blinded and study participants and the trial team/researchers conducting the intervention and assessing the outcomes will be blinded

**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**

تبریز

**Province**

East Azarbaijan

**Postal code**

3658745698

**Approval date**

2019-10-24, 1398/08/02

**Ethics committee reference number**

IR.TBZMED.REC.1398.759

**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**

Anthropometric indices

**Timepoint**

Measurement of body weight at baseline (before

intervention) and 6 and 12 weeks after omega-3 and / or turmeric supplementation

**Method of measurement**

Seca digital scale

**2**

**Description**

Glucose homeostasis (fasting glucose and insulin concentration)

**Timepoint**

Measurement of glucose homeostasis at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

**Method of measurement**

Biochemical analysis

**3**

**Description**

Cardiometabolic risk markers (triglycerides, total cholesterol, LDL cholesterol, HDL cholesterol and VLDL cholesterol)

**Timepoint**

Measurement of cardiometabolic risk markers at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

**Method of measurement**

Biochemical analysis

**4**

**Description**

Gene expression of vascular endothelial growth factor

**Timepoint**

Measurement of Gene expression of vascular endothelial growth factor at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

**Method of measurement**

Biochemical analysis

**Secondary outcomes**

**1**

**Description**

Serum concentration of inflammatory indices (hs-CRP)

**Timepoint**

Measurement the serum levels of inflammatory markers at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

**Method of measurement**

Biochemical analysis

**2**

**Description**

Serum concentration of oxidative stress indices (MDA and TAC)

**Timepoint**

Measurement the serum levels of oxidative stress indices at baseline (before intervention) and 12 weeks after omega-3 and / or turmeric supplementation

**Method of measurement**

Biochemical analysis

**Intervention groups**

**1**

**Description**

Intervention group 1: Daily intake of two 1000 mg omega-3 capsules (Zahravi pharma co.) and two 500 mg turmeric capsules (made by Dineh Company) for 12 weeks after meals

**Category**

Treatment - Other

**2**

**Description**

Intervention group 2: Daily intake of two 500 mg turmeric capsules (made by Dineh Company) and two omega-3 placebo capsules containing sunflower oil and for 12 weeks after meals

**Category**

Treatment - Other

**3**

**Description**

Intervention group 3: Daily intake of two 1000 mg omega-3 capsules (Zahravi pharma co.) and two turmeric placebo capsules for 12 weeks after meals

**Category**

Treatment - Other

**4**

**Description**

Control group: Daily intake of two turmeric placebo capsules and two omega-3 placebo capsules containing sunflower oil and for 12 weeks after meals

**Category**

Treatment - Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Emam Reza hospital

**Full name of responsible person**

Neda Dolatkah

**Street address**

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

**City**

تبریز

**Province**

East Azarbaijan

**Postal code**

5163995479

**Phone**

+98 41 3336 1928

**Email**  
neda\_dolatkhah@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Tabriz University of Medical Sciences

**Full name of responsible person**  
Mohammad Samiei

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

**City**  
Tabriz

**Province**  
East Azarbaijan

**Postal code**  
6532598756

**Phone**  
+98 41 3334 4280

**Email**  
samiei.moh@gmail.com

#### 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**  
Neda Dolatkhah

**Position**  
Assistant professor

**Latest degree**  
Ph.D.

**Other areas of specialty/work**  
Nutrition

**Street address**  
Emam Reza hospital, Golgasht Str., Azadi Ave., Tabriz

**City**  
Tabriz

**Province**

East Azarbaijan

**Postal code**  
5163995479

**Phone**  
0984133361928

**Email**  
neda\_dolatkhah@yahoo.com

## Person responsible for scientific 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

**Street address**  
Emam Reza hospital, Golgasht Str., Azadi Ave., Tabriz

**City**  
Tabriz

**Province**  
East Azarbaijan

**Postal code**  
5163995479

**Phone**  
+98 41 3336 1928

**Email**  
neda\_dolatkhah@yahoo.com

## Person responsible for updating data

#### 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

**Street address**  
Emam Reza hospital, Golgasht Str., Azadi Ave., Tabriz

**City**  
Tabriz

**Province**  
East Azarbaijan

**Postal code**  
5163995479

**Phone**  
+98 41 3336 1928

**Email**  
neda\_dolatkhah@yahoo.com

## **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