

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The effect of Anethum graveolens supplementation on some blood biochemical parameters in type 2 Diabetes Patients

#### Protocol summary

##### Summary

This study is a randomized double-blind placebo controlled trial that will carry on 60 diabetic patients according to specialist diagnosis from clinics of Tabriz University of Medical Science. The aim of the study is to evaluate the effect of Anethum graveolens supplementation on some blood biochemical parameters in type 2 Diabetes Mellitus patients. Patients will be divided randomly to 2 groups; intervention group : patients receive 3 pill containing 1g powder of anethum herb, and placebo group patients take 3 pill containing 1g isomalt capsule for 60 days. Anthropometric measurements (weight, height, waist and hip circumference), biochemical criteria including lipid profile (TG,TC,HDL-C,LDL-C), inflammation markers (hs-CRP, IL-6, TNF-a) , blood glucose and serum antioxidants using 5cc blood collected, physical activity levels and dietary record will be measured before and after treatment (8 week).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201112312017N6**

Registration date: **2012-01-10, 1390/10/20**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2012-01-10, 1390/10/20

##### Registrant information

##### Name

Alireza Ostadrahimi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

##### Email address

ostadrahimi@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice-chancellor for Research, Tabriz University Of Medical Sciences

##### Expected recruitment start date

2012-01-21, 1390/11/01

##### Expected recruitment end date

2012-03-20, 1391/01/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Anethum graveolens supplementation on some blood biochemical parameters in type 2 Diabetes Patients

##### Public title

The effect of Anethum graveolens supplementation on some blood biochemical parameters in type 2 Diabetes Patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: age between 18-65 years; proven diagnosis for diabetes mellitus; absence of antioxidants supplementation in previous months or in the study and absence of special diet. Exclusion criteria: history of impaired immune system; alcohol use and depression.

##### Age

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

**Placebo**

Used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Vice-chancellor for research-Tabriz University of Medical Science

**Street address**

Golgasht street, Tabriz, East Azarbayjan,Iran, Islamic Republic Of

**City**

Tabriz

**Postal code**

**Approval date**

2011-10-23, 1390/08/01

**Ethics committee reference number**

5.4.5842

**Health conditions studied**

**1**

**Description of health condition studied**

Diabetes type2

**ICD-10 code**

E11

**ICD-10 code description**

Non-insulin-dependent diabetes mellitus

**Primary outcomes**

**1**

**Description**

Lipid profiles (TC, TG, LDL-C, HDL-C)

**Timepoint**

Baseline and at the end of intervention

**Method of measurement**

Enzymatic methods for TC,TG and HDL-C For LDL-C :  
Freidwald's formula:  $LDL-C = TC - HDL-C - (TG/5)$

**2**

**Description**

Inflammation markers (hs-CRP , TNF- $\alpha$ .IL-6)

**Timepoint**

Baseline and at the end of intervention

**Method of measurement**

ELISA

**3**

**Description**

Blood glucose

**Timepoint**

Baseline and at the end of intervention

**Method of measurement**

Enzymatic method

**Secondary outcomes**

**1**

**Description**

Serum Antioxidant

**Timepoint**

Baseline and at the end of intervention

**Method of measurement**

enzymatic method

**2**

**Description**

Nutritional status

**Timepoint**

Baseline and at the end of intervention

**Method of measurement**

Dietary record and food frequency questionnaire

**3**

**Description**

Anthropometric measurements

**Timepoint**

Baseline and at the end of intervention

**Method of measurement**

Analogue scale and meter

**Intervention groups**

**1**

**Description**

Intervention group: daily 3 pill of containing 1g powder of Anethum herb for 60 day

**Category**

Treatment - Drugs

## 2

### Description

Placebo group: 3 pill containing 1g powder of isomalt for 60 day

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Tabriz University of Medical Sciences Clinics

##### Full name of responsible person

Laleh Payahoo

##### Street address

Health and Nutrition faculty, Attare Neishabouri Avenue, Golgasht street, Tabriz , East Azarbayjan ,Iran, Islamic Republic Of

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice-chancellor for research of Tabriz University of Medical Sciences

##### Full name of responsible person

Mohammadreza Rashidi

##### Street address

Tabriz University Of Medical Sciences, Tabriz, East Azarbaijan, Iran

##### City

Tabriz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Vice-chancellor for research of Tabriz University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

*empty*

##### Domestic or foreign origin

*empty*

##### Category of foreign source of funding

*empty*

##### Country of origin

##### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

### Name of organization / entity

Tabriz university of medical science

### Full name of responsible person

Laleh Payahoo

### Position

MSc student in Nutrition

### Other areas of specialty/work

### Street address

Health and Nutrition faculty, Attare Neishabouri Avenue, Golgasht street, Tabriz East Azarbayjan Iran, Islamic Republic Of

### City

Tabriz

### Postal code

### Phone

+98 41 1335 2295

### Fax

### Email

llllpayahoo44@gmail.com

### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz university of medical science

#### Full name of responsible person

Alireza Ostadrahimi

#### Position

Assistant professor in Nutrition

#### Other areas of specialty/work

#### Street address

Health and Nutrition faculty, Attare Neishabouri Avenue, Golgasht street, Tabriz, East Azarbayjan, Iran, Islamic Republic Of

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ostadrahimi@tbzmed.ac.ir llllpayahoo44@gmail.com

#### Web page address

## Person responsible for updating data

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Laleh Payahoo

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MSc student in Nutrition

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**Web page address**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*