

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

**The effect of ellagic acid supplementation on glycemic indices, lipid profile, anthropometric, inflammatory and oxidative indices, dietary intake and serum levels of pentosidine, adiponectin and resistin in patients with types 2: a double-blind, randomized controlled clinical trial**

### Protocol summary

#### Study aim

Determining the effect of supplementing with ellagic acid on serum levels of adiponectin, resistin, some inflammatory, oxidative indices and metabolic parameters in patients with type 2 diabetes

#### Design

Clinical trial with control group, with parallel groups, double-blind, randomized on 60 patients. ras software was used for randomization.

#### Settings and conduct

Sampling in this study will be from patients referred to Asad Abadi Hospital in Tabriz. During the intervention period, researchers and patients will not be aware the type of supplement received. The intervention period will be for 60 days and all parameters will be evaluated at the beginning and end of the study. During the intervention period, all patients will be followed up and the participants will be asked to visit each month to receive the capsules.

#### Participants/Inclusion and exclusion criteria

The inclusion criteria of the study include people with type 2 diabetes of both genders (patients who have been diagnosed with type 2 diabetes for at least 1 year) who are willing to participate in the project and are in the age range of 30-60 years, and with the use of oral medicine, their blood sugar is optimally controlled. The exclusion criteria include people treated with insulin, corticosteroids, non-steroidal anti-inflammatory drugs, and blood lipid-lowering drugs, as well as suffering from diseases such as cardiovascular diseases, polycystic ovary syndrome, kidney disease, hypothyroidism, and hyperthyroidism.

#### Intervention groups

The selected people were randomly assigned into two groups receiving the supplement (one capsule containing 250 mg of ellagic acid daily) and the placebo group (one

capsule containing 250 mg of microcrystalline cellulose daily).

#### Main outcome variables

Inflammatory; oxidative stress; metabolic; Anthropometry indicators

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20121028011288N18**

Registration date: **2022-10-26, 1401/08/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-10-26, 1401/08/04**

Update count: **0**

#### Registration date

2022-10-26, 1401/08/04

#### Registrant information

##### Name

Mohammad Alizadeh

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7313

##### Email address

mdalizadeh@tbzmed.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-10-21, 1401/07/29  
**Expected recruitment end date**  
2023-04-20, 1402/01/31  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

### Scientific title

The effect of ellagic acid supplementation on glycemic indices, lipid profile, anthropometric, inflammatory and oxidative indices, dietary intake and serum levels of pentosidine, adiponectin and resistin in patients with types 2: a double-blind, randomized controlled clinical trial

### Public title

The effect of Ellagic acid supplementation in patients with type 2 diabetes

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

patients with type 2 diabetes Using blood sugar lowering medicine Age range of 30-60 years BMI in the range of 25-35 1 to 15 years duration of type 2 diabetes Tendency of corpulence

#### Exclusion criteria:

Use of corticosteroids, steroidal and non-steroidal anti-inflammatory drugs Prescribing insulin Suffering from chronic diseases such as heart failure, kidney, liver and thyroid disorders

### Age

From **30 years** old to **60 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Investigator

### Sample size

Target sample size: **46**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The block randomization method will be used observing equal number 6-number blocks (including n=3 for intervention group and n=3 for placebo group). Random allocation software (RAS) will be used for generating sequential numbers. For blinding, concealment allocation method will be implemented using sealed, opaque envelopes.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this study, the main investigators as well as the patients will be blinded to the type of supplements received by 2 groups. The person responsible for

preparing the supplements boxes ( who is completely unrelated to the study) will be asked to assign a 3 digit code to each of the capsules ( supplement or placebo ) and keep the codes for himself until the end of the study and data analyses.

### 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

Tabriz University Of Medical Sciences, Golghasht St

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5166614711

#### Approval date

2022-08-21, 1401/05/30

#### Ethics committee reference number

IR.TBZMED.REC.1401.445

## Health conditions studied

### 1

#### Description of health condition studied

type 2 diabetes

#### ICD-10 code

E11

#### ICD-10 code description

Type 2 diabetes mellitus

## Primary outcomes

### 1

#### Description

Serum level of pentosidine

#### Timepoint

At the beginning of the study and 60 days later

#### Method of measurement

ELISA kit

### 2

#### Description

Serum level of adiponectin

**Timepoint**

At the beginning of the study and 60 days later

**Method of measurement**

ELISA kit

**3****Description**

Serum level of resistine

**Timepoint**

At the beginning of the study and 60 days later

**Method of measurement**

ELISA kit

**4****Description**

fasting blood sugar

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

Enzymatic kit

**5****Description**

total cholesterol

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

Enzymatic kit

**6****Description**

Serum triglyceride

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

Enzymatic kit

**7****Description**

HDL serum level

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

Enzymatic kit

**8****Description**

LDL serum level

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

Farid Wald's formula

**9****Description**

Serum insulin level

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

ELISA kit

**10****Description**

Hemoglobin A1c

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

ELISA kit

**11****Description**

Weight

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

Digital scale

**12****Description**

height

**Timepoint**

The beginning of the study and 60 days later

**Method of measurement**

Tape measure

**Secondary outcomes****1****Description**

Energy intake level

**Timepoint**

At the beginning of the study and 60 days later

**Method of measurement**

3-day Food Record Questionnaire

**2****Description**

Macronutrients intake level

**Timepoint**

At the beginning of the study and 8 weeks later

**Method of measurement**

3-day Food Record Questionnaire

**Intervention groups****1****Description**

Intervention group: Patients in this group will receive 1capsules of 250 milligrams of ellagic acid (product by Exir Gostar Espadana Co. and made in The Iran) for 8 consecutive weeks a day.

**Category**

Treatment - Other

## 2

### Description

Control group: Control group: Patients in this group will receive microcrystalline cellulose capsules( product by Exir Gostar Espadana Co. and made in The Iran), once a day and for 8 consecutive weeks which will be same in terms of shapem size and color with those used for the intervention group.

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Diabetes Association of East Azarbaijan Province

##### Full name of responsible person

Dr. Mohammad Alizadeh

##### Street address

Tabriz University of Medical Sciences, Golgasht St

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

mdalizadeh@tbzmed.ac.ir

##### Web page address

<http://nutr.tbzmed.ac.ir/?PageID=128&ID=37&BasesID=140>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr.Shahabi

##### Street address

Vice Chancellor for Research No 2 Central Building,  
Tabriz University of Medical Sciences, Daneshgah  
Street, Tabriz

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##### Province

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##### Email

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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

Ayda Najmi

##### Position

Master's student in clinical nutrition

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nutrition

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Alizadeh

##### Position

professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

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**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

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Ayda Najmi

**Position**

University student

**Latest degree**

Bachelor

**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**

Demographic and primary outcomes data of participants

**When the data will become available and for how long**

Accessibility to data is possible 6 months after publication.

**To whom data/document is available**

Researchers who are working in academic institutes

**Under which criteria data/document could be used**

Only observation of documents is allowed; Analysis and use of data is not possible.

**From where data/document is obtainable**

mdalizadeh@tbzmed.ac.ir, 09141894102 2

aydanjmy6@gmail.com, 09144325240

**What processes are involved for a request to access data/document**

The applicant can send her request to the person in charge of the study through email, and the documents will be sent to the applicant in the shortest possible time.

**Comments**