

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### The effects of pomegranate seed oil supplementation on the PPAR gamma and GLUT4 genes expression and the serum levels of IL-6, TNF- $\alpha$ and hs-CRP inflammatory factors and Glycemic indexes in obese type 2 diabetic patients: randomized controlled clinical tri

#### Protocol summary

##### Study aim

determining the effects of pomegranate seed oil supplementation on the PPAR gamma and GLUT4 genes expression and the serum levels of IL-6, TNF- $\alpha$  and hs-CRP inflammatory factors and Glycemic indexes in obese type 2 diabetic patients

##### Design

this study will be done on 60 type 2 diabetic patients in both genders. Subjects will be randomly divided into two intervention and control groups by considering the inclusion criteria (age between 30 to 50 years, BMI greater than 30 and less than 40, and fasting glucose equal to or greater than 126) and non- inclusion criteria (Pregnant women, lactating women, hormone replacement therapy, taking TZD and insulin medications) of the study.

##### Settings and conduct

This randomized, controlled clinical trial is conducted on obese patients with type 2 diabetes who are referred to Tabriz University of Medical Sciences clinics with a duration of more than 6 months. After entering the study, the subjects will be divided into two groups of intervention and control by simple randomization. The intervention group will receive 3 gr pomegranate seed oil softgels) 1 gr each( daily and the control group will receive similar amounts of placebo (paraffin) for 8 weeks. People are asked to take a softgel with breakfast, lunch, and dinner. Five cc fasting blood samples will collect from all participants at the beginning and end of the intervention. All the participant will complete short form of the International Physical Activity Questionnaire and 3-day food record at the beginning and end of the intervention.

##### Participants/Inclusion and exclusion criteria

this study will be done on 60 type 2 diabetic patients in both genders. Inclusion criteria (age between 30 to 50

years, BMI greater than 30 and less than 40, and fasting glucose equal to or greater than 126) and Exclusion criteria (Pregnant women, lactating women, hormone replacement therapy, taking TZD and insulin medications)

##### Intervention groups

The intervention group will receive 3 gr pomegranate seed oil softgels) 1 gr each( daily and the control group will receive similar amounts of placebo (paraffin) for 8 weeks.

##### Main outcome variables

PPAR gamma and GLUT4 genes expression; The serum levels of IL-6, TNF- $\alpha$  and hs-CRP inflammatory factors; Glycemic indexes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100606004105N15**

Registration date: **2017-12-27, 1396/10/06**

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

Last update: **2017-12-27, 1396/10/06**

Update count: **0**

##### Registration date

2017-12-27, 1396/10/06

##### Registrant information

##### Name

Beit Allah Alipour

##### Name of organization / entity

Health & Nutrition Faculty

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7580

**Email address**

alipourb@tbzmed.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Tabriz University of Medical Sciences

**Expected recruitment start date**

2017-12-22, 1396/10/01

**Expected recruitment end date**

2018-03-16, 1396/12/25

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effects of pomegranate seed oil supplementation on the PPAR gamma and GLUT4 genes expression and the serum levels of IL-6, TNF- $\alpha$  and hs-CRP inflammatory factors and Glycemic indexes in obese type 2 diabetic patients: randomized controlled clinical tri

**Public title**

Effect of pomegranate seed oil on obese type 2 diabetic patients

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Age between 30 to 50 years BMI greater than 30 and less than 40 Fasting glucose equal to or greater than 126 Having a willingness and ability to cooperate in the study

**Exclusion criteria:**

Pregnant women Lactating women, Patients under hormone therapy Patients who taking TZD or Insulin medications Patients who taking lipid-lowering medications Patients who taking weight loss medications Patients who didn't take antioxidants drugs (at least 3 months ago) Patients with impaired fat metabolism Patients who have allergies to pomegranate Patients who consumed less than 90% of pomegranate seed oil, changed their dose of medicine Patients who taking vitamins (D, A, B6), and omega 3 supplements Patients who do not have the desire or ability to continue studying

**Age**

From **30 years** old to **50 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Convenience Sampling

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

All capsules with same shapes and colors were placed by a third person who labeled the bottles with 2 codes which remained unknown to the researchers until the end of assays

**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, Golgasht street

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5165687386

**Approval date**

2017-12-04, 1396/09/13

**Ethics committee reference number**

IR.TBZMED.REC.1396.748

**Health conditions studied**

1

**Description of health condition studied**

type 2 diabetes

**ICD-10 code**

E11

**ICD-10 code description**

Non-insulin-dependent diabetes mellitus

2

**Description of health condition studied**

obesity

**ICD-10 code**

E66

**ICD-10 code description**

obesity

## Primary outcomes

**1**

### Description

Fasting insulin

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Autoanalyzer kit

**2**

### Description

Hemoglobin A1C

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Autoanalyzer kit

**3**

### Description

high- sensitive C-reactive protein of Serum

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

ELISA

**4**

### Description

serum interleukin-6

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

ELISA

**5**

### Description

serum tumor necrosis factor-alpha

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

ELISA

**6**

### Description

Glucose transporter type 4 gene expression

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Real time PCR

**7**

### Description

peroxisome proliferator-activated receptors gamma gene expression

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Real time PCR

**8**

### Description

Serum triglycerides

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Autoanalyzer kit

**9**

### Description

serum low density lipoprotein cholesterol

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Autoanalyzer kit

**10**

### Description

serum high density lipoprotein cholesterol

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Autoanalyzer kit

**11**

### Description

total cholesterol

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Autoanalyzer kit

**12**

### Description

fasting blood glucose

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Autoanalyzer kit

**13**

### Description

insulin resistance

### Timepoint

Before and the end of the intervention (eighth week)

### Method of measurement

Homeostasis model (HOMA-IR)

**14**

### Description

insulin sensitivity

### Timepoint

Before and the end of the intervention (eighth week)

#### Method of measurement

QUICKI

### Secondary outcomes

#### 1

##### Description

body mass index

##### Timepoint

Before and at the end of the intervention (eighth week)

##### Method of measurement

the body mass divided by the square of the body height

#### 2

##### Description

fat mass

##### Timepoint

Before and at the end of the intervention (eighth week)

##### Method of measurement

bioelectrical impedance

### Intervention groups

#### 1

##### Description

Placebo (Paraffin): 3 Soft Gel (1 gr each) with Meals of Breakfast, Lunch and Dinner for 8 weeks

##### Category

Placebo

#### 2

##### Description

3 pomegranate seed oil soft gels (1 gr each) with Meals of Breakfast, Lunch and Dinner daily for 8 weeks

##### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Bahar Clinic

###### Full name of responsible person

Yaser khajebishak

###### Street address

Tabriz- goltasht ST

###### City

Tabriz

###### Province

East Azarbaijan

###### Postal code

5165687386

###### Phone

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###### Email

alipourb@tbzmed.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Full name of responsible person

Dr Abolghasem Jouyban

###### Street address

Vice-chancellor for Research, Tabriz University of Medical Sciences

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Tabriz

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###### Email

research-vice@tbzmed.ac.ir

##### 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

Faculty of Nutrition and Food Sciences

##### Full name of responsible person

Yaser khajebishak

##### Position

Ph.D. Student in Nutrition

##### Latest degree

Master

##### Other areas of specialty/work

Nutrition

##### Street address

Attar-e Nishaboori ST- Faculty of Nutrition and Food Sciences

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##### Province

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**Email**

khajebishaky@tbzmed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Faculty of Nutrition and Food Sciences, Tabriz  
university of Mdical Sciences

**Full name of responsible person**

Dr. Beit Allah Alipour

**Position**

Professor of Nutrition, in Faculty of Nutrition and Food  
Sciences

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Faculty of Nutrition and Food Sciences

**Full name of responsible person**

Yaser khajebishak

**Position**

Ph.D. student in Nutrition

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

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**Web page address**

## 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**

Not applicable

**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