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-α 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-α 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-α 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)

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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-α 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- golgasht ST

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5165687386

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

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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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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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