

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of pomegranate juice (no added sugar) consumption on lipid profile, inflammation factor and oxidative stress in overweight or obese patients with type 2 diabetes

Protocol summary

Summary

The aim of this randomized double blind clinical trial is to determine the effects of pomegranate juice on some blood biochemical parameters in type 2 diabetic patients. Fifty patients aged between 30-50 years old from both sexes are assigned into two groups. Patients in intervention group consume 250ml/day pomegranate juice and patients in control group consume 250ml/day water for 8 weeks. Anthropometric and blood pressure measurements, 3 times 3-day food record and fasting blood samples are collected at the beginning and at the end of study. Fasting blood sugar, glycosylated hemoglobin, insulin, lipid profile, malondialdehyde (MDA), total antioxidant capacity (TAC), superoxide dismutase, glutathione peroxidase and hsCRP are measured. LDL and HOMA-IR are calculated by formula. The participants are asked not to change their regular diet, medicine and activity during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138904294424N1**
Registration date: **2010-10-18, 1389/07/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-10-18, 1389/07/26

Registrant information

Name

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Name of organization / entity

Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Nutrition research center, Tabriz University of Medical Sciences & Shadli Company

Expected recruitment start date

2010-05-31, 1389/03/10

Expected recruitment end date

2010-08-01, 1389/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pomegranate juice (no added sugar) consumption on lipid profile, inflammation factor and oxidative stress in overweight or obese patients with type 2 diabetes

Public title

The effects of pomegranate juice on type 2 diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: male or female, 30 to 50 years old, BMI between 25-35, having type 2 diabetes at least 6 month, taking metformin or glybanclamid, taking atrovastain, simvastatin or levostatin. Exclusion criteria: having the renal or hepatic failure, treatment With HRT, smoking,

treatment with insulin, use of multivitamin-mineral 6 months prior to the study.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Golbad Ave

City

Tabriz

Postal code

Approval date

2010-09-27, 1389/07/05

Ethics committee reference number

8926

Health conditions studied

1

Description of health condition studied

diabetes mellitus 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

baseline and after 8 weeks

Method of measurement

spectrophotometry

2

Description

Hemoglobin A1c

Timepoint

baseline and after 8weeks

Method of measurement

Chromatography

3

Description

Insulin

Timepoint

baseline and after 8 weeks

Method of measurement

ELIZA

4

Description

HOMA-IR

Timepoint

Baseline and after 8weeks

Method of measurement

Formula

5

Description

Total Cholesterol

Timepoint

Baseline and after8 weeks

Method of measurement

Spectrophotometry

6

Description

Triglyceride

Timepoint

Baseline and after8 weeks

Method of measurement

Spectrophotometry

7

Description

HDL

Timepoint

Baseline and after 8 weeks

Method of measurement

Spectrophotometry

8

Description

LDL

Timepoint

Baseline and after 8 weeks

Method of measurement

Friedewald Formula

9

Description

Malondialdehyde

Timepoint

Baseline and after 8 weeks

Method of measurement

Spectrophotometry

10

Description

Glutathione peroxidase

Timepoint

Baseline and after 8 weeks

Method of measurement

Spectrophotometry

11

Description

Superoxide dismutase

Timepoint

Baseline and after 8 weeks

Method of measurement

Spectrophotometry

12

Description

Total Antioxidant Capacity (TAC)

Timepoint

Baseline and after 8 weeks

Method of measurement

Spectrophotometry

13

Description

hsCRP

Timepoint

baseline and after 8 weeks

Method of measurement

immunoturbidometry

Secondary outcomes

1

Description

Dietary Factors

Timepoint

Baseline and after 8 weeks

Method of measurement

3-day food record

2

Description

Body Mass Index

Timepoint

Baseline and after 8 weeks

Method of measurement

Formula

3

Description

Blood Pressure

Timepoint

Baseline and after 8 weeks

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

intervention Group:pomegranate juice,250 ml/day,8weeks

Category

Treatment - Drugs

2

Description

Control Group:water,250 ml/day,8 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Endocrine Clinic

Full name of responsible person

Dr. Ebrahimi

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ebrahimi

Street address

Golbad street

City

Tabriz
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
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

2

Sponsor
Name of organization / entity
Nutrition research center, Tabriz university of Medical sciences
Full name of responsible person
Dr Alireza Ostadrahimi
Street address
Faculty of Health & Nutrition, Atar-Neishaboori st, Golgasht st
City
Tabriz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nutrition research center, Tabriz university of Medical sciences
Proportion provided by this source
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

3

Sponsor
Name of organization / entity
Shadli company
Full name of responsible person
Mrs Soltani
Street address
Urumie
City
Urumie
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shadli company
Proportion provided by this source
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
Faculty of Health and Nutrition, Tabriz University of Medical Sciences
Full name of responsible person
Dr. Ebrahimi
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Associate Professor in Department of nutrition in society
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Person responsible for scientific inquiries

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Person responsible for updating data

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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