Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Samira Babayian Amini

Name of organization / entity

Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 407 5580

Email address

ebrahimiemamagani@tbzmed.ac.ir

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 8weeks
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
immunotorbidometry

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

Position

Associate Professor in Department of nutrition in society

Other areas of specialty/work

Street address

Attar Neyshabouri Street, Golgasht Street

City

Tabriz

Postal code

Phone

+98 41 1335 7580

Fax

Email

ebrahimimamagani@tbzmed.ac.ir , samira_b_amini@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Samira Babayian Amini

Position

MSc Student of Nutrition Science

Other areas of specialty/work

Street address

Attar Neyshabouri Street, Golgasht Street

City

Tabriz

Postal code

Phone

+98 914 407 5580

Fax

Email

samira_b_amini@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Samira Babayian Amini

Position

MSc Student of Nutrition Science

Other areas of specialty/work

Street address

City

Postal code

Phone

Fax

Email

samira_b_amini@yahoo.com

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