

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Effects of Pomegranate juice consumption on serum vascular and systematic inflammation factors, advanced glycation end products, NF-kB and Sirtuin1 activity in mononuclear cells in type2 diabetic patients

Protocol summary

Summary

Cardiovascular diseases, nephropathy, blindness and amputation are the main complications of diabetes mellitus. These complications are mainly because of micro and macro angiopathy. High serum concentrations of oxidative stress, inflammation markers and advanced glycated end products are important risk factors for the development of diabetic complications. Pomegranate juice has antioxidant and anti-inflammatory properties. The purpose of this study is to determine the effects of pomegranate juice consumption on serum vascular and systematic inflammation factors, advanced glycation end products, NF-kB and Sirtuin1 activity in mononuclear cells in type2 diabetic patients. This study is a randomized double blind clinical trial performs on 48, 40-65 years old diabetic patients recruit from "Special Diabetic Affairs Foundation". The patients are randomly allocated either to pomegranate juice consumption group or control group. PJ and control group will ask to consume 240 ml/day of PJ (without added sugar or additives) or a control beverage of similar color and energy and glucose content for 3 months. The questionnaires of general characters and three days 24-hour food recall will be completed by interview. Anthropometric measurements will be measured and 20 ml blood collected from each patient after 12-14h overnight fasting, at baseline and at the end of the study. Data will be analyzed using SPSS software. Independent-T-test will be used to compare pre and post intervention variables between groups. Covariance analysis will be used to compare blood parameters of two groups at the end of the study, adjusted for baseline measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206144010N8**

Registration date: **2012-07-12, 1391/04/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-07-12, 1391/04/22

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
National Institute of Nutrition Research

Country

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Recruitment status

Recruitment complete

Funding source

Institute of Nutrition And Food Sciences ; Research
Institute for Endocrine Sciences

Expected recruitment start date

2012-06-21, 1391/04/01

Expected recruitment end date

2012-07-21, 1391/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Pomegranate juice consumption on serum vascular and systematic inflammation factors, advanced glycation end products, NF- κ B and Sirtuin1 activity in mononuclear cells in type2 diabetic patients

Public title

Effects of pomegranate juice consumption on diabetes complications

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Diabetes type 2; 40-65 years old; BMI=18.5-30; Control of diabetes only by oral agents. Exclusion criteria: Liver and kidney diseases; Inflammatory diseases; Consumption of multivitamin and/or mineral supplements in the past 3 months; Consumption of corticosteroid, anti-inflammatory, non-steroid medications; Changing in type and dosage of used medications during the study; Changing in physical activity type and levels, during the study.

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **48**

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**

Institute of Nutrition and Food Sciences

Street address

No 9, West Arghavan, Farahzadi Blvd, Shahrak Qods

City

Tehran

Postal code

1981619573

Approval date

2011-11-28, 1390/09/07

Ethics committee reference number

043435

Health conditions studied**1****Description of health condition studied**

diabetes type 2

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus

Primary outcomes**1****Description**

TNF- α

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/L

2**Description**

hs-CRP

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/mL

3**Description**

IL-6

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/L

4**Description**

ICAM-1

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/mL

5**Description**

VCAM-1

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/mL

6

Description

E-selectin

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/mL

7

Description

Pentosidine

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/mL

8

Description

Carboxy Methyl Lysin

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/mL

9

Description

HbA1C

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

Cromatography, Percent

10

Description

Glucose

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

calorimetry, mg/dl

11

Description

Insulin

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA, mU/L

12

Description

HOMA-IR

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

Calculate,(glucosexInsulin)/22.5

13

Description

NF-kB activity

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA

14

Description

Srtuin1 activity

Timepoint

at baseline and after 3 months at the end of the study

Method of measurement

ELISA , ng/mL

Secondary outcomes

empty

Intervention groups

1

Description

240 ml/day of PJ (without added sugar or additives) providing 126 Kcal, fat 0g, protein 1.4 g, and 23.5 g sugar for 3 months

Category

Other

2

Description

240 ml/day of a control beverage of similar color and energy and glucose content for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Nutrition Sciences and Food technology, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golbon Sohrab

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Institute of Nutrition Sciences and Food technology

Full name of responsible person
Dr Majid Hajifaraji

Street address
No 9, West Arghavan, Farahzadi Blvd, Shahrak Qods

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Institute of Nutrition Sciences and Food technology

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
Research Institute for Endocrine Sciences

Full name of responsible person
professor Fereidoun Azizi

Street address
No 24, Parvaneh St., Yaman St., Velenjak

City
Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Institute for Endocrine 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

Person responsible for general inquiries

Contact

Name of organization / entity
Faculty of Nutrition Sciences and Food technology,
Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golbon Sohrab

Position
PhD student in Nutrition Sciences

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

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