# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Jun 2026

## The effect of concentrated pomegranate juice consumption on lipid profile and inflammatory factors in patients with type 2 diabetes

## Protocol summary

**Summary**

The aim of this study is to examine the effects of concentrated pomegranate juice on serum lipid profile and some inflammatory factors in patients with type 2 diabetes. Forty patients aged between 25-60 years old from both sexes are recruited. Patients consume 50gr/day concentrated pomegranate juice for 4 weeks. Anthropometric and blood pressure measurements, 3-days food-record questionnaire ,physical activity and fasting blood samples were collected at the beginning and at the end of the study. Fasting blood sugar, lipid profile, TNF- a, IL-6,hs –CRP and adiponectin levels are measured. LDL 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: **IRCT2013091614680N1**
Registration date: **2013-11-22, 1392/09/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2013-11-22, 1392/09/01

**Registrant information**

**Name**

Farideh Shishehbor

**Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

**Country**

Iran (Islamic Republic of)

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**Recruitment status**

**Recruitment complete**

**Funding source**

Vic chancellor for research, Ahvaz Jundishapour University of Medical Sciences

**Expected recruitment start date**

2013-10-02, 1392/07/10

**Expected recruitment end date**

2013-12-01, 1392/09/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of concentrated pomegranate juice consumption on lipid profile and inflammatory factors in patients with type 2 diabetes

**Public title**

The effects of concentrated pomegranate juice on inflammatory factors in type 2 diabetes

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

Inclusion criteria: male or female 25 to 60 years old; having type 2 diabetes at least 6 month. Exclusion criteria: pregnancy; lactation; cardiac; hepatic; respiratory and chronic renal diseases; acute or chronic inflammation; retinopathy; intake of antioxidant supplement; insulin therapy; sensitivity to concentrated pomegranate juice; change oral drug for controlling blood glucose were excluded.

**Age**

From **25 years** old to **60 years** old

**Gender**

Both

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **40**
**Randomization (investigator's opinion)**
N/A
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Single
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ahvaz Jundishapoor University of Medical Sciences
**Street address**
Vice Chancellor for Research and Technological Development, Ahvaz Jundishapoor University of Medical Sciences, Golestan Blv., Ahvaz
**City**
Ahvaz
**Postal code**
**Approval date**
2013-06-22, 1392/04/01
**Ethics committee reference number**
Ajums-REC.1392.54 B-9202

## Health conditions studied

### 1

**Description of health condition studied**
type 2 diabetes
**ICD-10 code**
E-11
**ICD-10 code description**
Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

**Description**
Triglyceride
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**
Spectrophotometry

### 2

**Description**
Total Cholesterol
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**
Spectrophotometry

### 3

**Description**
HDL- Cholesterol
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**
Spectrophotometry

### 4

**Description**
LDL- Cholesterol
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**
Friedewald Formula

### 5

**Description**
hsCRP
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**
Eliza

### 6

**Description**
TNF- α
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**
Eliza

### 7

**Description**
IL-6
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**
Eliza

### 8

**Description**
adiponectin
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**

Eliza

## Secondary outcomes

**1**

**Description**
Fasting Blood Sugar
**Timepoint**
baseline and after 4 weeks
**Method of measurement**
Spectrophotometry

**2**

**Description**
Blood Pressure
**Timepoint**
Baseline and after 4 weeks
**Method of measurement**
Sphygmomanometer

**3**

**Description**
Body Mass Index
**Timepoint**
baseline and after 4 weeks
**Method of measurement**
calculate

## Intervention groups

**1**

**Description**
50 gr concentrated pomegranate juice with lunch and dinner meals for 4 weeks
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Golestan hospital
**Full name of responsible person**
**Street address**
**City**
Ahvaz

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vic chancellor for research, Ahvaz Jundishapour University of Medical Sciences
**Full name of responsible person**
Maryam Zare
**Street address**
Ahvaz Jundishapour University of Medical Sciences
**City**
Ahvaz
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Vic chancellor for research, Ahvaz Jundishapour University of Medical Sciences
**Proportion provided by this source**
100
**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**
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## Person responsible for scientific inquiries

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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*