

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effects of cranberry juice on serum glucose, apoB, apoA-I, Lp(a) and Paraoxonase-1 activity in type 2 diabetic male patients.

Protocol summary

Summary

This study was undertaken to assess the effect of consumption of 1 cup cranberry juice by type 2 diabetic patients on serum paraoxonase-1 (PON-1) activity, apoA-1, apoB, glucose and Lp(a). In a double-blind randomized clinical trial, 58 type2 diabetic male patients were randomly divided to received 1 cup cranberry juice (CJ) or placebo drink daily for 12 weeks. Inclusion criteria were BMI more than 30 kg/m² and HbA1c less than 9%. Exclusion criteria were change in the use of medication for diabetes; hypertension; dyslipidemia or anti-platelet in the previous 2 months; pregnancy or breastfeeding. There were significant decrease in serum glucose and apoB ($p < 0.05$ and $p < 0.01$, respectively) and significant increase in serum apoA-1 and PON-1 activity ($p < 0.05$ and $p < 0.01$, respectively) at the end of study in CJ group compare to control group. Conclusion: 1 cup cranberry juice for 12 weeks is effective in reducing serum glucose and apoB and increasing apoA-1 and PON-1 activity, so may have favorable effects on reducing CVD risk factors in type 2 diabetic male patients

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201111272709N23**

Registration date: **2011-12-24, 1390/10/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-12-24, 1390/10/03

Registrant information

Name

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Name of organization / entity

Iran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2009-08-15, 1388/05/24

Expected recruitment end date

2011-03-23, 1390/01/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of cranberry juice on serum glucose, apoB, apoA-I, Lp(a) and Paraoxonase-1 activity in type 2 diabetic male patients.

Public title

The Effects of cranberry juice in type 2 diabetic male patients.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: BMI more than 30 kg/m²; HbA1c less than 9%; serum triglyceride < 400mg/dl; serum total cholesterol < 240mg/dl; taking oral hypoglycemic agents but not insulin. Exclusion criteria: A recent (within previous 3 months) or past history of symptomatic heart disease; myocardial infarction; angina pectoris or stroke

; surgery ; liver ; renal (plasma creatinine >1.62 mg/dl) or thyroid disease; use of steroids or drugs with unknown components ; change in the use of medication for diabetes ; hypertension ; dyslipidemia or anti-platelet in the previous 2 months ; pregnancy or reastfeeding.

Age

From **25 years** old to **70 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **58**

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

School of Medicine, Tehran University of Medical sciencesa

Street address

Central building of Tehran University of Medical Sciences, Intersection of Qods Avenue and Bulvar Keshavarz

City

Tehran

Postal code

Approval date

2010-01-18, 1388/10/28

Ethics committee reference number

3248

Health conditions studied

1

Description of health condition studied

IV Endocrine, nutritional and metabolic diseases

ICD-10 code

E(E00-E90)

ICD-10 code description

E11

Primary outcomes

1

Description

Lp(a)

Timepoint

12 weeks

Method of measurement

Laboratory kits

2

Description

glucose

Timepoint

12 weeks

Method of measurement

laboratory kits

3

Description

Paraoxonase-1

Timepoint

12 weeks

Method of measurement

Laboratory kits

4

Description

ApoB

Timepoint

12 weeks

Method of measurement

laboratory kits

5

Description

Apoa-I

Timepoint

12 weeks

Method of measurement

laboratory kits

Secondary outcomes

1

Description

Weight

Timepoint

12 weeks

Method of measurement

electronic scale

2

Description

Body mass index

Timepoint

12 weeks

Method of measurement

Weight/height²

3

Description

Waist circumference

Timepoint

12 weeks

Method of measurement

nonstretchable tape

Intervention groups

1

Description

A double-blind randomized clinical trial of parallel design was used. During a 2-week baseline period, participants continued their usual diet without any cranberry (Run-in period), then in intervention group Patients consumed 1 cup (240ml) cranberry juice (CJ group) for 12 weeks. Thirty, nonsmoking type 2 diabetes (T2D) male patients were recruited from the Endocrine Research Center of Tehran University of Medical sciences (TUMS), Tehran, Iran from Sep 2009 to March 2011. All patients were asked to maintain their usual diet and physical activity level and not to alter their lifestyle during the intervention. Twenty-nine patients in intervention group ended the study.

Category

Treatment - Other

2

Description

A double-blind randomized clinical trial of parallel design was used. During a 2-week baseline period, participants continued their usual diet without any cranberry (Run-in period), then in control group patients consumed 1 cup (240ml) placebo drink (natural mineral water with strawberry flavor) for 12 weeks. Thirty, nonsmoking type 2 diabetes (T2D) male patients were recruited from the Endocrine Research Center of Tehran University of Medical sciences (TUMS), Tehran, Iran from Sep 2009 to March 2011. All patients were asked to maintain their usual diet and physical activity level and not to alter their lifestyle during the intervention. Twenty-nine patients in control group ended the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and Research Center (Tehran University of Medical Sciences)

Full name of responsible person

Dr. mohammad ebrahim Khamseh

Street address

Endocrine and Research Center-Firozgar Education Center-Behafarin Avenue-Valiasr Square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Abbass motevalian

Street address

Deputy of Researches and Technology, Central Building of Tehran University of Medical Sciences, Intersection of Qods Avenue and Bulvar Keshavarz

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Name of organization / entity

Tehran University of Medical sciences

Full name of responsible person

Farzad Shidfar

Position

Associate Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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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