Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 2026

The effect of cranberry supplementation on glucose, lipid, oxidative stress, inflammation markers, fat mass distribution and blood pressure in overweight women with metabolic syndrome

Protocol summary

Summary
To evaluate the effect of cranberry supplement on long term complications in metabolic syndrome, 50 metabolic syndrome women aged 20-50 years old were recruited from Shiraz healthy heart house. The women were randomly assigned into the two groups to receive 2 cranberry supplements equal to 400 mg fruit extract or placebo for 2 months. At baseline and at the end of the second month, the index of total cholesterol, HDL-cholesterol, LDL-cholesterol, triglycerides, IL-6, hsCRP, adiponectin, blood glucose, MDA, insulin and blood pressure will be measured.

General information

Acronym
IRCT registration information
IRCT registration number: **IRCT201110192480N2**
Registration date: **2012-01-21, 1390/11/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**
Registration date
2012-01-21, 1390/11/01

Registrant information
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Recruitment status
Recruitment complete
Funding source
Shiraz University of Medical Sciences

Expected recruitment start date
2011-11-06, 1390/08/15
Expected recruitment end date
2012-02-04, 1390/11/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of cranberry supplementation on glucose, lipid, oxidative stress, inflammation markers, fat mass distribution and blood pressure in overweight women with metabolic syndrome

Public title
Effect of cranberry supplement on long-term consequences of metabolic syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: Women with features of metabolic syndrome between 20 and 50 years of age, BMI>25. Exclusion criteria: Postmenopausal women; medications for any chronic disease (cancer, diabetes, CVD); use of medication known to affect lipid metabolism or possess anti-inflammatory effect; Smoking; Alcohol consumption; use of supplements (antioxidants, multivitamins,...); Chronic disease: renal, liver, thyroid, etc; pregnant or lactating; use of warfarin.
Age
From **20 years** old to **50 years** old
Gender

Female

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
Shiraz University of Medical Sciences
Street address
Central Medical Building, Zand Avenue, PO Box 1978-71345
City
Shiraz
Postal code
vcrdep@sums.ac.ir
Approval date
2011-10-09, 1390/07/17
Ethics committee reference number
CT-90-5726

Health conditions studied

1

Description of health condition studied
metabolic syndrome
ICD-10 code
Z86.3
ICD-10 code description
Personal history of endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description
lipid profile
Timepoint
Before and 2 months after intervention
Method of measurement
Auto analyzer

2

Description
FBS
Timepoint
Before and 2 months after intervention
Method of measurement
Auto analyzer

3

Description
Systolic and diastolic blood pressure
Timepoint
Before and 2 months after intervention
Method of measurement
Mercury Barometer

4

Description
Waist circumference
Timepoint
Before and 2 months after intervention
Method of measurement
Tape Meter

Secondary outcomes

1

Description
Insulin
Timepoint
Before and 2 months after intervention
Method of measurement
ELISA kit

2

Description
Interlukin-6 (IL-6)
Timepoint
Before and 2 months after intervention
Method of measurement
RIA

3

Description
hsCRP
Timepoint
Before and 2 months after intervention
Method of measurement
ELISA kit

4

Description

adiponectin
Timepoint
Before and 2 months after intervention
Method of measurement
ELISA kit

5

Description
malon-dialdehide(MDA)
Timepoint
Before and 2 months after intervention
Method of measurement
Spectrophotometry

Intervention groups

1

Description
Cranberry supplements intake is equivalent to 400 mg fruit extract per day, for 2 months
Category
Treatment - Drugs

2

Description
placebo intake for 2 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Healthy Heart House
Full name of responsible person
Street address
Across from St. Fazilat, Modares Blvd
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz university of medical sciences
Full name of responsible person
Mohammad Hassan Eftekhari
Street address
Central medical building, Zand avenue
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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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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