

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Clinical trial comparing the effects of Vaccinium arctostaphylos fruit extract with placebo on the blood levels of glycosylated hemoglobin and LDL-cholesterol, amounts of systolic and diastolic blood pressures, body mass index and waist circumference in hypertensive obese patients

Protocol summary

Summary

Objective: Comparing the effects of Vaccinium arctostaphylos fruit extract on cardiometabolic indices with placebo in hypertensive obese patients. Study design: randomized, double-blind, placebo-controlled, two group parallel design, single-center, phase 2 of clinical trial. Study population: Hypertensive obese patients. Sample size: 100 patients. Inclusion criteria: Iranian male and female hypertensive obese outpatients; patients aged 30 to 80 years; patients with body mass index between 25 kilograms per square meter and 35 kilograms per square meter; patients with systolic blood pressures between 14 and 16 mmHg; patients with diastolic blood pressures between 8 and 10 mmHg; patients taking synthetic antihypertensive drugs with 2 different mechanisms. Exclusion criteria: Patients taking other drugs effective on the blood glucose and lipid levels and body weight; patients with cardiac, renal, hepatic, hematological diseases, hypothyroidism, tachycardia, vertigo and seizure; patients with a history of gallstones or gall bladder surgery; pregnant women; women planning pregnancy; breast-feeding women. Interventions: Vaccinium arctostaphylos fruit extract is administered at the dose of one 400 mg capsule every 8 hours to a group of 50 patients for 3 months and one placebo capsule is administered every 8 hours to another group of 50 patients for 3 months. Before intervention and 3 months after intervention, the primary and secondary outcome variables are evaluated. Primary outcome variables: Blood levels of glycosylated hemoglobin and LDL-C, amounts of systolic and diastolic blood pressures, body mass index, waist circumference. Secondary outcome variables: Blood levels of fasting glucose, total cholesterol, triglyceride, HDL-C, creatinine, SGOT and SGPT.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT201710302288N12**

Registration date: **2017-11-15, 1396/08/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-15, 1396/08/24

Registrant information

Name

Saeed Kianbakht

Name of organization / entity

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

Country

Iran (Islamic Republic of)

Phone

+98 26147640109

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Research Institute for Islamic and Complementary Medicine

Expected recruitment start date

2017-06-22, 1396/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Clinical trial comparing the effects of Vaccinium arctostaphylos fruit extract with placebo on the blood levels of glycosylated hemoglobin and LDL-cholesterol, amounts of systolic and diastolic blood pressures, body mass index and waist circumference in hypertensive obese patients

Public title
Effects of vaccinium arctostaphylos fruit on cardiometabolic indices in hypertensive obese patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Iranian male and female hypertensive obese outpatients; patients aged 30 to 80 years; patients with body mass index between 25 kilograms per square meter and 35 kilograms per square meter; patients with systolic blood pressures between 14 and 16 mmHg; patients with diastolic blood pressures between 8 and 10 mmHg; patients taking synthetic antihypertensive drugs with 2 different mechanisms. Exclusion criteria: Patients taking other drugs effective on the blood glucose and lipid levels and body weight; patients with cardiac, renal, hepatic, hematological diseases, hypothyroidism, tachycardia, vertigo and seizure; patients with a history of gallstones or gall bladder surgery; pregnant women; women planning pregnancy; breast-feeding women.

Age
From **30 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

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

Research Institute for Islamic and Complementary Medicine

Street address

Number 9, Pirnia Alley, Lalehzar Shomali Street, Jomhoori Eslami Avenue

City

Tehran

Postal code

1145847111

Approval date

2017-06-16, 1396/03/26

Ethics committee reference number

IR.IUMS.REC.1396.31591

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66.0

ICD-10 code description

Obesity due to excess calories

2

Description of health condition studied

Hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Blood level of glycosylated hemoglobin

Timepoint

Before and after 3 months of intervention

Method of measurement

Kit

2

Description

Blood level of low density lipoprotein cholesterol

Timepoint

Before and after 3 months of intervention

Method of measurement

Kit

3

Description

Body mass index

Timepoint

Before and after 3 months of intervention

Method of measurement

Scale and tape measure

4

Description

Waist circumference

Timepoint

Before and after 3 months of intervention

Method of measurement

Tape measure

5

Description

Systolic blood pressure

Timepoint

Before and after 3 months of intervention

Method of measurement

24-hour ambulatory blood pressure monitoring

6

Description

Diastolic blood pressure

Timepoint

Before and after 3 months of intervention

Method of measurement

24-hour ambulatory blood pressure monitoring

Secondary outcomes

1

Description

Fasting blood glucose level

Timepoint

Before and after 3 months of intervention

Method of measurement

Kit

2

Description

Blood total cholesterol level

Timepoint

Before and after 3 months of intervention

Method of measurement

Kit

3

Description

Blood triglyceride level

Timepoint

Before and after 3 months of intervention

Method of measurement

kit

4

Description

Blood high density lipoprotein cholesterol level

Timepoint

Before and after 3 months of intervention

Method of measurement

Kit

5

Description

Blood serum glutamate oxaloacetate transaminase level

Timepoint

Before and after 3 months of intervention

Method of measurement

Kit

6

Description

Blood serum glutamate pyruvate transaminase level

Timepoint

Before and after 3 months of intervention

Method of measurement

Kit

7

Description

Blood creatinine level

Timepoint

Before and after 3 months of intervention

Method of measurement

Kit

Intervention groups

1

Description

Vaccinium arctostaphylos fruit extract is administered at the dose of one 400 mg capsule every 8 hours to a group of 50 patients for 3 months

Category

Treatment - Drugs

2

Description

One placebo capsule is administered every 8 hours to a group of 50 patients for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatallah Hospital
Full name of responsible person
Dr. Reza Mohtashami
Street address
Molla Sadra street, Vanak square
City
Tehran

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skianbakht@yahoo.com; kianbakht@imp.ac.ir
Web page address
www.imp.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, Research Institute for
Islamic and Complementary Medicine
Full name of responsible person
Dr. Fataneh Hashem Dabaghian
Street address
Number 9, Pirnia Alley, Lalehzar Shomali Street,
Jomhoori Eslami Avenue
City
Tehran
Grant name
96-105-2937
Grant code / Reference number
96-105-2937
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Vice Chancellor for Research, Research Institute for
Islamic and Complementary Medicine
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
ACECR Institute of Medicinal Plants
Full name of responsible person
Dr. Saeed Kianbakht
Position
Ph.D. in pharmacology, assistant professor of the
department of pharmacology and applied medicine in
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Institute of Medicinal Plants, ACECR Complex, Supa
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Person responsible for updating data

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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