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)

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+98 26147640109

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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-choletserol, 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 choletserol 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 cholesterlol 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 glutatamate 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 adminstered 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

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

Other areas of specialty/work

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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