Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Clinical trial comparing the effects of Vaccinium arctostaphylos leaf and fruit extracts with placebo on the blood levels of glycosylated hemoglobin and LDL-cholesterol and amounts of systolic and diastolic blood pressures in the hypertensive hyperlipidemic type 2 diabetic patients

Protocol summary

Summary

Objective: Comparing the efficacy of Vaccinium arctostaphylos leaf and fruit extracts with placebo in the treatment of hypertensive hyperlipidemic type 2 diabetic patients. Study design: randomized, double-blind, placebo-controlled, three group parallel design, single-center, phase 2 of clinical trial. Study population: Hypertensive hyperlipidemic type 2 diabetic patients. Sample size: 150 patients. Inclusion criteria: Iranian male and female hypertensive hyperlipidemic type 2 diabetic outpatients; patients aged 40 to 60 years; patients with blood HbA1c levels between 7% and 9%; patients with fasting blood LDL levels between 100 mg/dL and 150 mg/dL; patients with systolic blood pressures between 14 and 16 mmHg; patients with diastolic blood pressures between 9 and 10 mmHg; patients taking 15 mg glibenclamide, 2 g metformin and 20 mg atorvastatin per day; patients taking synthetic antihypertensive drugs with 3 different mechanisms per day. Exclusion criteria: Patients taking other drugs effective on the blood glucose and lipid levels; 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: Each of the Vaccinium arctostaphylos leaf and fruit extracts are administered separately to a group of 50 patients at the dose of one 350 mg capsule every 8 hours for 2 months and one placebo capsule is administered to another group of 50 patients every 8 hours for 2 months. Before intervention and 2 months after intervention, the primary and secondary outcome variables are evaluated. Primary outcome variables: Blood levels of glycosylated hemoglobin and LDL-C and amounts of systolic and diastolic blood pressures. Secondary outcome variables: Blood levels of fasting glucose, 2 hour postprandial glucose, total cholesterol, triglyceride, HDL-C, creatinine, SGOT and SGPT.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701282288N11**
Registration date: **2017-02-12, 1395/11/24**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-12, 1395/11/24

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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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, ACECR Institute of

Medicinal Plants

Expected recruitment start date
2013-04-21, 1392/02/01
Expected recruitment end date
2017-06-22, 1396/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Clinical trial comparing the effects of Vaccinium arctostaphylos leaf and fruit extracts with placebo on the blood levels of glycosylated hemoglobin and LDL-cholesterol and amounts of systolic and diastolic blood pressures in the hypertensive hyperlipidemic type 2 diabetic patients

Public title
Study on efficacy of Vaccinium arctostaphylos in the treatment of hypertensive hyperlipidemic type 2 diabetic patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Iranian male and female hypertensive hyperlipidemic type 2 diabetic outpatients; patients aged 40 to 60 years; patients with blood HbA1c levels between 7% and 9%; patients with fasting blood LDL levels between 100 mg/dL and 150 mg/dL; patients with systolic blood pressures between 14 and 16 mmHg; patients with diastolic blood pressures between 9 and 10 mmHg; patients taking 15 mg glibenclamide, 2 g metformin and 20 mg atorvastatin per day; patients taking synthetic antihypertensive drugs with 3 different mechanisms per day. Exclusion criteria: Patients taking other drugs effective on the blood glucose and lipid levels; 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 **40 years** old to **60 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Block randomization with computer generated random numbers table and sequentially numbered containers each representing a block consisting of three patients are used for the treatment assignments.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Endocrinology and Metabolism Research Institute
Street address
Shariati Hospital, Northern Kargar Avenue
City
Tehran
Postal code
1411413137
Approval date
2011-02-10, 1389/11/21
Ethics committee reference number
E-00104

Health conditions studied

1

Description of health condition studied
Diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Amount of systolic blood pressure
Timepoint
2 months
Method of measurement
24-hour ambulatory blood pressure monitoring

2

Description
Amount of diastolic blood pressure
Timepoint
2 months
Method of measurement
24-hour ambulatory blood pressure monitoring

3

Description
Blood level of glycosylated hemoglobin
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

4

Description
Blood level of LDL-C
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

Secondary outcomes

1

Description
Blood level of HDL-C
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

2

Description
Blood level of total choletsterol
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

3

Description
Blood level of SGOT
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

4

Description
Blood level of SGPT
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

5

Description
Blood level of creatinine
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

6

Description
Fasting blood glucose level
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

7

Description
2 hour postprandial blood glucose level
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

8

Description
Blood level of triglycerides
Timepoint
2 months
Method of measurement
Medical laboratory (kit)

Intervention groups

1

Description
Vaccinium arctostaphylos fruit extract at the dose of one 350 mg capsule every 8 hours in addition to standard treatments is administered to a group of 50 patients for 2 months.
Category
Treatment - Drugs

2

Description
Vaccinium arctostaphylos leaf extract at the dose of one 350 mg capsule every 8 hours in addition to standard treatments is administered to a group of 50 patients for 2 months.
Category
Treatment - Drugs

3

Description
One placebo capsule every 8 hours in addition to standard treatments is adminstered to a group of 50 patients for 2 months.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
The Diabetes and Metabolic Diseases Clinic of the Tehran University of Medical Sciences

Full name of responsible person
Dr. Kamelia Rambod

Street address
Western Shahrivar Street, Northern Kargar Avenue

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research, ACECR Institute of Medicinal Plants

Full name of responsible person
Dr. Reza Hajiaghaee

Street address
ACECR Complex, Supa Boulevard, Poleh Kordan

City
Karaj

Grant name
1988-20

Grant code / Reference number
1988-20

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

Title of funding source
Vice Chancellor for Research, ACECR Institute of Medicinal Plants

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