

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 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 cholesterol

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 administered 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

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Boulevard, Poleh Kordan

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Web page address

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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
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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