

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Study on Efficacy of Vaccinium arctostaphylos (L.) Fruit Extract in Treatment of Hyperlipidemic Patients

Protocol summary

Summary

Objective: study on efficacy of Vaccinium arctostaphylos (L.) fruit extract in the treatment of hyperlipidemic patients. Study population: hyperlipidemic patients coming to the Diabetes Clinic in Karaj. Sample size: 60 patients. Inclusion criteria: patients aged 20 to 60 years, patients with serum cholesterol level above 240 mg/dl, patients with serum triglyceride level above 240 mg/dl, patients recently diagnosed as hyperlipidemic, literate patients. Exclusion criteria: patients with serum cholesterol or triglyceride levels above 300 mg/dl, patients using other blood lipid lowering agents, patients with cardiac, renal, hepatic, hematological diseases, hypothyroidism, diabetes, tachycardia, vertigo and seizure, patients with a history of gallstones or gall bladder surgery, patients using estrogen, steroid, beta-blocker and thiazide, pregnant women, women planning pregnancy, breast-feeding women. The intervention: Caucasian whortleberry fruit extract is administered to a group of 30 patients at the dose of one 500 mg capsule every 8 hours for 2 months and placebo is administered to another group of 30 patients every 8 hours for 2 months. At the end of the study, the blood lipids levels in the drug group and the placebo group are determined and compared with each other. Primary outcomes: Blood serum level of cholesterol, blood serum level of triglyceride.

General information

Acronym

SEVAFETHP

IRCT registration information

IRCT registration number: **IRCT201112242288N4**

Registration date: **2011-12-28, 1390/10/07**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-12-28, 1390/10/07

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

kianbakht@imp.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Institute for Islamic and Complementary Medicine

Expected recruitment start date

2012-01-21, 1390/11/01

Expected recruitment end date

2013-01-20, 1391/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on Efficacy of Vaccinium arctostaphylos (L.) Fruit Extract in Treatment of Hyperlipidemic Patients

Public title

Study on efficacy of Caucasian whortleberry in the treatment of hyperlipidemic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 20 to 60 years, patients with serum cholesterol level above 240 mg/dl, patients with serum triglyceride level above 240 mg/dl, patients recently diagnosed as hyperlipidemic, literate patients. Exclusion criteria: patients with serum cholesterol or triglyceride levels above 300 mg/dl, patients using other blood lipid lowering agents, patients with cardiac, renal, hepatic, hematological diseases, hypothyroidism, diabetes, tachycardia, vertigo and seizure, patients with a history of gallstones or gall bladder surgery, patients using estrogen, steroid, beta-blocker and thiazide, pregnant women, women planning pregnancy, breast-feeding women.

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Ethics Committee of 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

2011-10-08, 1390/07/16

Ethics committee reference number

89

Health conditions studied

1

Description of health condition studied

Hyperlipidemia

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidemia, unspecified

Primary outcomes

1

Description

Blood serum cholesterol level of patients

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

2

Description

Blood serum triglyceride level of patients

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

Secondary outcomes

1

Description

Blood serum LDL cholesterol level of patients

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

2

Description

Blood serum HDL cholesterol level of patients

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

3

Description

Blood serum creatinine level of patients

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

4

Description

Blood serum SGOT level of patients

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

5

Description

Blood serum SGPT level of patients

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

Intervention groups

1

Description

Caucasian whortleberry fruit extract is administered to a group of about 30 patients at the dose of one 500 mg capsule every 8 hours for 2 months.

Category

Treatment - Drugs

2

Description

One placebo capsule is administered to another group of about 30 patients every 8 hours for 2 months

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Clinic of diabetes

Full name of responsible person

Dr. Behrouz Abasi Alaei

Street address

Number 448, Street Bareghan, Square Azadegan

City

Karaj

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Research Institute for Islamic and Complementary
Medicine

Full name of responsible person

Dr. Dabaghian

Street address

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

City

Tehran

Grant name

702

Grant code / Reference number

702

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

Yes

Title of funding source

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**

Institute of Medicinal Plants affiliated with the ACECR

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**Street address**

Institute of Medicinal Plants, Research Complex of the
ACECR, End of Kavosh Boulevard, Kavosh Research
Town, 55th Kilometer of Tehran-Gazvin Freeway

City

Karaj

Postal code

2378965473

Phone

+98 26147640109

Fax

+98 26 1476 4021

Email

kianbakht@imp.ac.ir; skianbakht@gmail.com

Web page address

www.imp.ac.ir

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Institute of Medicinal Plants affiliated with the ACECR

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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Fax

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Email

kianbakht@imp.ac.ir; skianbakht@gmail.com

Web page address

www.imp.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

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Web page address

www.imp.ac.ir

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