

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Study on efficacy of *Vaccinium arctostaphylos* (L.) fruits extract in treatment of type 2 diabetic patients

Protocol summary

Summary

Objective: Study on efficacy of *Vaccinium arctostaphylos* L. fruits extract in treatment of type 2 diabetic patients. Study population: type 2 diabetic patients attending the Karaj diabetes clinic. Inclusion criteria: type 2 diabetic patients, patients aged 40 to 60 years, patients with fasting glucose serum levels between 200 and 250 mg/dl, patients with glycosylated hemoglobin blood levels between 6.5 and 8 percents, patients whose blood glucose levels are not within the normal range despite using a combination of oral synthetic antidiabetic drugs. Exclusion criteria: patients with cardiac, renal or hepatic diseases, concomitant infections, pregnant women, women planning pregnancy, breast-feeding women. The intervention: The Caucasian whortleberry fruits extract is administered to a group of about 30 patients at the dose of one 500 mg capsule every 8 hours in addition to the oral synthetic antidiabetic drugs for 2 months and placebo is administered to another group of about 30 patients every 8 hours in addition to the oral synthetic antidiabetic drugs for 2 months. At the end of the study, the fasting glucose, 2 hours postprandial glucose and glycosylated hemoglobin blood levels in the drug group and the placebo group are determined and compared with each other.

General information

Acronym

SEVAFETDP

IRCT registration information

IRCT registration number: **IRCT138902292288N3**

Registration date: **2010-06-12, 1389/03/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2010-06-12, 1389/03/22

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

2010-09-23, 1389/07/01

Expected recruitment end date

2011-09-23, 1390/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on efficacy of *Vaccinium arctostaphylos* (L.) fruits extract in treatment of type 2 diabetic patients

Public title

Study on efficacy of Caucasian whortleberry in treatment of type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: type 2 diabetic patients, patients aged 40 to 60 years, patients with fasting glucose serum levels between 200 and 250 mg/dl, patients with glycosylated hemoglobin blood levels between 6.5 to 8 percent, patients whose blood glucose levels are not within the normal range despite using a combination of oral synthetic antidiabetic drugs. Exclusion criteria: patients with cardiac, renal or hepatic diseases, concomitant infections, pregnant women, women planning pregnancy, breast-feeding women.

Age

From **40 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**

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

2010-12-05, 1389/09/14

Ethics committee reference number

238/tm/p26

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus type 2

Primary outcomes**1****Description**

Fasting glucose serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

2**Description**

Glycosylated hemoglobin blood level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

Secondary outcomes**1****Description**

2 hours postprandial glucose serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

Intervention groups**1****Description**

Caucasian whortleberry fruits extract, one 500 mg
capsule every 8 hours in addition to the oral synthetic
antidiabetic drugs for 2 months

Category

Treatment - Drugs

2**Description**

One placebo capsule every 8 hours in addition to the oral
synthetic antidiabetic drugs 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 Bareghhan, Square Azadegan
City
Karaj

Karaj
Postal code
2378965473
Phone
+98 26 1476 4010
Fax
+98 26 1476 4021
Email
kianbakht@imp.ac.ir, skianbakht@gmail.com
Web page address
www.imp.ac.ir

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
238
Grant code / Reference number
238
**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

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
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 26 1476 4010
Fax
+98 26 1476 4021
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
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 26 1476 4010

Fax

+98 26 1476 4021

Email

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

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