Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 26147640109

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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 Alaee
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
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

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Other areas of specialty/work
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Person responsible for updating data

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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