

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the effect of Vaccinium arctostaphylos fruit alcoholic extract on serum levels of inflammatory factors in adult patients with hyperlipidemia

Protocol summary

Summary

The aim of this clinical trial to evaluate the effects of Vaccinium arctostaphylos on hyperlipidemia. Inclusion criteria: Patients serum levels of total cholesterol 200–300 mg/dL and/or triglyceride (TG) 150–199 mg/dL and/or LDL-C 130–190 mg/dL. 40 patients with hyperlipidemia over of 18 years will be randomly divided into two treatment groups and control. In the treatment group take two tablets daily capsule of Vaccinium arctostaphylos, and in the control group take two placebo capsule for a month. At the beginning and end of a month will collect of blood samples for determination of ICAM-1, VCAM-1, IL-6, TNF α level. Also, determine the possible effect of the drug on liver and renal function Cr and ALT and AST liver enzymes to be determined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201507309662N10**

Registration date: **2015-09-16, 1394/06/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-09-16, 1394/06/25

Registrant information

Name

Sedigheh Asgari

Name of organization / entity

Isfahan Cardiovascular Research Center ,Isfahan
Cardiovascular Research institute , Physiology Re

Country

Iran (Islamic Republic of)

Phone

+98 31 1335 9090

Email address

s_asgari@crc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-10-23, 1394/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Vaccinium arctostaphylos fruit alcoholic extract on serum levels of inflammatory factors in adult patients with hyperlipidemia

Public title

Vaccinium arctostaphylos fruit on levels of inflammatory factors in adult patients with hyperlipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion/exclusion criteria: age over of 18 years; serum levels of total cholesterol 200–300 mg/dL and/or triglyceride (TG) 150–199 mg/dL and/or LDL-C 130–190 mg/dL; being non-smokers; free of diseases affecting serum lipids (e.g., diabetes, thyroid disorders, and pancreatitis); not using drugs or supplements affecting serum lipids (e.g., statins, fibrate derivatives, estrogens, progestins, beta-blockers, thiazide diuretics,

and fish oil) within the last 3 months; free of liver or kidney disease; nonpregnant, nonlactating women

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple 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 Isfahan University of Medical Sciences

Street address

Hezar jirib St. Isfahan, Iran

City

Isfahan

Postal code

Approval date

2011-09-23, 1390/07/01

Ethics committee reference number

393079

Health conditions studied

1

Description of health condition studied

Pure hypercholesterolaemia

ICD-10 code

E78.0

ICD-10 code description

Pure hypercholesterolaemia

2

Description of health condition studied

Hyperlipidaemia, unspecified

ICD-10 code

E78.5

ICD-10 code description

Hyperlipidaemia, unspecified

3

Description of health condition studied

Other disorders of lipoprotein metabolism

ICD-10 code

E78.8

ICD-10 code description

Other disorders of lipoprotein metabolism

Primary outcomes

1

Description

Intercellular adhesion molecule-1

Timepoint

Before and after one Month

Method of measurement

ELISA Kit

2

Description

vascular cell adhesion molecule-1

Timepoint

Before and after one Month

Method of measurement

ELISA Kit

3

Description

IL-6

Timepoint

Before and after one Month

Method of measurement

ELISA Kit

4

Description

TNF- α

Timepoint

Before and after one Month

Method of measurement

ELISA Kit

Secondary outcomes

1

Description

Weight

Timepoint

Before and after 4 weeks

Method of measurement

scale

2

Description

Creatinine level

Timepoint

Before and after One Month

Method of measurement

ELISA Kit

3

Description

Urea levels

Timepoint

Before and after One Month

Method of measurement

ELISA Kit

4

Description

Liver enzyme ALT

Timepoint

Before and after One Month

Method of measurement

ELISA Kit

5

Description

Liver enzyme AST

Timepoint

Before and after One Month

Method of measurement

ELISA Kit

Intervention groups

1

Description

control group: take placebo capsol twice a day for a month

Category

Placebo

2

Description

case group: take Vaccinium arctostaphylos capsol twice a day for a month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Cardiovascular Research Center

Full name of responsible person

Mahtab Keshvari

Street address

Khorram Street, Jomhori Square

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr.Gholam Hossin Sadri

Street address

Hezar jirib St.

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Isfahan University of Medical Sciences

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences

Full name of responsible person

Sedigheh Asgary

Position

Pharmacist and PhD Pharmacogenetics

Other areas of specialty/work

Street address

Khorram Street, Jomhoori Square

City

Isfahan

Postal code

Phone

+98 31 3335 9595

Fax

Email

sasgary@yahoo.com

Web page address

+98 31 3335 9595

Fax

Email

mahtabkeshvari87@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Isfahan Cardiovascular Research Center

Full name of responsible person

Mahtab keshvari

Position

MS / MS Research

Other areas of specialty/work

Street address

Khorram Street, Jomhoori Square

City

Isfahan

Postal code

Phone

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