

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Study on effects of *Cynara scolymus* L. leaf extract in treatment of hypercholesterolemic type 2 diabetic patients

Protocol summary

Summary

Objective: Study on effects of *Cynara scolymus* L. leaf extract in treatment of hypercholesterolemic type 2 diabetic patients. Study population: Hypercholesterolemic type 2 diabetic patients attending the diabetes clinic. Sample size: 60 patients. Inclusion criteria: Iranian male and female type 2 diabetic outpatients, patients aged 40 to 60 years, patients with fasting serum glucose levels from 150 mg/dl to 200 mg/dl, patients with blood HbA1c levels from 7% to 9% despite taking two 5 mg glyburide tablets and two 500 mg metformin tablets every day, patients using two 5 mg glyburide tablets and two 500 mg metformin tablets every day, patients with fasting serum LDL levels from 100 mg/dl to 150 mg/dl. Exclusion criteria: Patients taking other anti-hyperglycemic and anti-hyperlipidemic agents, patients receiving insulin, patients with cardiac, renal, hepatic, hematological diseases, hypothyroidism, 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. Intervention: The artichoke leaf extract is administered to a group of about 30 patients at the dose of one 400 mg capsule every 8 hours for 2 months and one placebo capsule is administered to another group of about 30 patients every 8 hours for 2 months. At the end of the study, the blood levels of fasting glucose, 2 hours postprandial glucose, glycosylated hemoglobin, lipids, creatinine and hepatic enzymes of the patients in the drug group and the placebo group are determined and compared with each other.

General information

Acronym

SECSTHT2DP

IRCT registration information

IRCT registration number: **IRCT201112252288N5**

Registration date: **2011-12-31, 1390/10/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-12-31, 1390/10/10

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

Institute of Medicinal Plants affiliated with ACECR

Expected recruitment start date

2011-03-21, 1390/01/01

Expected recruitment end date

2012-03-20, 1391/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study on effects of *Cynara scolymus* L. leaf extract in treatment of hypercholesterolemic type 2 diabetic patients

Public title

Study on effects of artichoke in treatment of hypercholesterolemic type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Iranian male and female type 2 diabetic outpatients, patients aged 40 to 60 years, patients with fasting serum glucose levels from 150 mg/dl to 200 mg/dl, patients with blood HbA1c levels from 7% to 9% despite taking two 5 mg glyburide tablets and two 500 mg metformin tablets every day, patients using two 5 mg glyburide tablets and two 500 mg metformin tablets every day, patients with fasting serum LDL levels from 100 mg/dl to 150 mg/dl. Exclusion criteria: Patients taking other anti-hyperglycemic and anti-hyperlipidemic agents, patients receiving insulin, patients with cardiac, renal, hepatic, hematological diseases, hypothyroidism, 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 **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**

Avicenna Research Institute affiliated with ACECR

Street address

Shahid Beheshti University, Shahid Chamran Freeway

City

Tehran

Postal code

1117719615

Approval date

2010-09-16, 1389/06/25

Ethics committee reference number

67/22/978

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**

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)

3**Description**

LDL serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

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

SGOT serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

2**Description**

SGPT serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

3**Description**

Total cholesterol serum level

Timepoint

2 months

Method of measurement

Medical laboratory (Kit)

4**Description**

VLDL serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

5**Description**

HDL serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

6**Description**

Triglyceride serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

7**Description**

Creatinine serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

8**Description**

2 hours postprandial glucose serum level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

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

Artichoke leaf extract at the dose of one 400 mg capsule

every 8 hours in addition to daily two 5 mg glyburide tablets and two 500 mg metformine tablets are administered to a group of about 30 patients for 2 months.

Category

Treatment - Drugs

2**Description**

One placebo capsule every 8 hours in addition to daily two 5 mg glyburide tablets and two 500 mg metformine tablets are administered to a group of about 30 patients for 2 months.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes clinic

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**

Jahade Daneshgahi

Full name of responsible person

Haji Tarverdi

Street address

Jahade Daneshgahi, Enghelab St.

City

Tehran

Grant name

48-1564

Grant code / Reference number

1564-48

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

Yes

Title of funding source

Jahade Daneshgahi

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

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Person responsible for updating data

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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