

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

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

Protocol summary

Summary

Objective: Study on effects of *Salvia officinalis* 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 blood HbA1c levels below 8%; patients with serum LDL levels from 100 mg/dl to 130 mg/dl; patients receiving standard therapy with synthetic anti-hyperglycemic and anti-hyperlipidemic drugs. Exclusion criteria: 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

SESOLEHT2DP

IRCT registration information

IRCT registration number: **IRCT201506082288N7**

Registration date: **2015-06-28, 1394/04/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-06-28, 1394/04/07

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

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Recruitment status

Recruitment complete

Funding source

Iranian Academic Center for Education, Culture and Research Institute of Medical Sciences

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Study on effects of sage 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 blood HbA1c levels below 8%; patients with serum LDL levels from 100 mg/dl to 130 mg/dl; patients receiving standard therapy with synthetic anti-hyperglycemic and anti-hyperlipidemic drugs. Exclusion criteria: 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
2

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

Tehran University of Medical Sciences Endocrinology and Metabolism Research Institute

Street address

North Kargar Avenue, Shariati hospital

City

Tehran

Postal code

1411413137

Approval date

2011-02-10, 1389/11/21

Ethics committee reference number

00104-E

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 serum glucose 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

Serum triglyceride level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

2

Description

Serum total cholesterol level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

3

Description

Serum creatinine level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

4

Description

Serum 2 hour postprandial glucose level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

5

Description

Serum SGOT level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

6

Description

Serum SGPT level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

7

Description

Serum HDL level

Timepoint

2 months

Method of measurement

Medical laboratory (kit)

8

Description

Body mass index

Timepoint

2 months

Method of measurement

Weighing scales and tape

Intervention groups

1

Description

Sage leaf extract at the dose of one 500 mg capsule every 8 hours besides synthetic anti-hyperglycemic and anti-hyperlipidemic drugs are administered to a group of about 30 patients for 2 months.

Category

Treatment - Drugs

2

Description

One placebo capsule every 8 hours besides synthetic anti-hyperglycemic and anti-hyperlipidemic drugs are administered to a group of about 30 patients for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center**Name of recruitment center**

Tehran University of Medical Sciences Diabetes Research Center

Full name of responsible person

Ms. Dr. Rambod

Street address

Kargar shomali Avenue, Shariati hospital

City

Tehran

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

Full name of responsible person

Dr. Saeed Kianbakht

Street address

Institute of Medicinal Plants, Research Complex of the Iranian Academic Center for Education, Culture and Research, End of Kavosh Boulevard, Kavosh Research Town, 55th Kilometer of Tehran-Gazvin Freeway

City

Karaj

Grant name

00104

Grant code / Reference number

00104

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

Yes

Title of funding source

Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

Proportion provided by this source**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

2

Sponsor

Name of organization / entity
Tehran University of Medical Sciences Diabetes
Research Center
Full name of responsible person
Ms. Dr. Rambod
Street address
Northern Kargar Avenue, Shariati hospital
City
Tehran
Grant name
00104
Grant code / Reference number
00104
**Is the source of funding the same sponsor
organization/entity?**
Yes
Title of funding source
Tehran University of Medical Sciences Diabetes Research
Center
Proportion provided by this source
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

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Iranian Academic Center for Education, Culture and
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Full name of responsible person
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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