Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study on Efficacy of Salvia officinalis (L.) Leaves Extract in Treatment of Hyperlipidemic Patients

Protocol summary

Summary

Objective: study on efficacy of Salvia officinalis (L.) leaves extract in the treatment of hyperlipidemic patients. Study population: hyperlipidemic patients of the outpatient clinic in the Qom Kamkar hospital. Sample size: 60 patients. Inclusion criteria: patients aged 20 to 60 years, patients with serum cholesterol level above 240 mg/dl, patients with serum triglyceride level above 200 mg/dl, patients recently diagnosed as hyperlipidemic, literate patients. Exclusion criteria: patients with serum cholesterol or triglyceride levels above 300 mg/dl, patients with cardiac, renal, hepatic, hematological diseases, hypothyroidism, diabetes, 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. The intervention: Sage leaves extract is administered to a group of 30 patients at the dose of one 500 mg capsule every 8 hours for 1 month and placebo is administered to another group of 30 patients every 8 hours for 1 month. At the end of the study, the blood lipids levels in the drug group and the placebo group are determined and compared with each other.

General information

Acronym
SESOLETHP

IRCT registration information
IRCT registration number: **IRCT138805132288N1**
Registration date: **2009-11-15, 1388/08/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date
2009-11-15, 1388/08/24

Registrant information

Name
Saeed Kianbakht

Name of organization / entity
Iranian Academic Center for Education, Culture and Research Institute of Medicinal Plants

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Research Institute for Islamic and Complementary Medicine

Expected recruitment start date
2009-12-22, 1388/10/01

Expected recruitment end date
2010-12-22, 1389/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Study on Efficacy of Salvia officinalis (L.) Leaves Extract in Treatment of Hyperlipidemic Patients

Public title
Study on efficacy of sage in the treatment of hyperlipidemic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients aged 20 to 60 years, patients with serum cholesterol level above 240 mg/dl, patients

with serum triglyceride level above 200 mg/dl, patients recently diagnosed as hyperlipidemic, literate patients. Exclusion criteria: patients with serum cholesterol or triglyceride levels above 300 mg/dl, patients with cardiac, renal, hepatic, hematological diseases, hypothyroidism, diabetes, 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 **20 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
Randomized double-blind placebo-controlled clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of 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
empty

Ethics committee reference number
78

Health conditions studied

1

Description of health condition studied
Hyperlipidemia

ICD-10 code
E78.5

ICD-10 code description
Hyperlipidemia, unspecified

Primary outcomes

1

Description
Decrease of the blood serum cholesterol level in patients

Timepoint
1 month

Method of measurement
Medical laboratory (kit)

2

Description
Decrease of the blood serum triglyceride level in patients

Timepoint
1 month

Method of measurement
Medical laboratory (kit)

Secondary outcomes

1

Description
Decrease of the blood serum LDL cholesterol level in patients

Timepoint
1 month

Method of measurement
Medical laboratory (kit)

2

Description
Dcrease of the blood serum VLDL lipoprotein level in patients

Timepoint
1 month

Method of measurement
Medical laboratory (kit)

3

Description
Increase of the blood serum HDL cholesterol level in patients

Timepoint
1 month

Method of measurement
Medical laboratory (kit)

Intervention groups

1

Description
one placebo capsule is administered to another group of about 30 patients every 8 hours for 1 month
Category
Placebo

2

Description
Sage leaves extract is administered to a group of about 30 patients at the dose of one 500 mg capsule every 8 hours for 1 month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamkar Hospital
Full name of responsible person
Dr. Mahmood Parham
Street address
Dey 19 Street
City
Qom

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
658
Grant code / Reference number
658
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
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Person responsible for scientific inquiries

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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