

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 26147640109

Email address

kianbakht@imp.ac.ir

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

Street address

Institute of Medicinal Plants, Research Complex of the ACECR, End of Kavosh Boulevard, Kavosh Research Town, 55th Kilometer of Tehran-Gazvin Freeway

City

Karaj

Postal code

2378965473

Phone

+98 26 1476 4010

Fax

+98 26 1476 4021

Email

kianbakht@imp.ac.ir, skianbakht@gmail.com

Web page address

www.imp.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Faculty of Medicine of Qom University of Medical Sciences

Full name of responsible person

Dr. Akram Heidari

Position

Specialist in community medicine

Other areas of specialty/work

Street address

Department of Community Medicine, Faculty of Medicine, Golestan Alley, Number 2 Alley, Moallem Jonubi Avenue

City

Qom

Postal code

3713645612

Phone

+98 25 1783 1370

Fax

+98 25 1773 7923

Email

heidari6@muq.ac.ir, heidari6@yahoo.com

Web page address
www.muq.ac.ir

Person responsible for updating data

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

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Fax

+98 26 1476 4021

Email

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