Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Effect of Salvia officinalis Tablet on lipid profile and quality of life in postmenopausal women

Protocol summary

Study aim
The effect of sage on serum lipids and quality of life in postmenopausal women

Design
Clinical trial with control group, with parallel groups, double-blind, randomized by permutation method

Settings and conduct
The researcher-made demographic information questionnaire and the quality of life questionnaire of postmenopausal women are completed by the researcher. The samples are controlled for serum lipids, including cholesterol, triglycerides, LDL and HDL. They are then intervened with medication or placebo for 8 weeks. The intervention is in the form of oral tablets of 100 mg of sage extract or placebo three times a day. At the end of 8 weeks, the questionnaire of quality of life of postmenopausal women is completed again by the researcher and the tests are repeated, and the results are compared and statistically analyzed. Will be located.The study site is health centers in Shiraz.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Menopausal women between the ages of 45-60, without any serious physical or mental illness, without any use of hormonal drugs, with body mass index less than 29, no smoking, no allergies. Exclusion criteria: use of hormonal drugs, beta-blocker, thiazide, allergy, use of any drug that affects menopause, blood lipid level more than 300mg

Intervention groups
After obtaining informed consent and providing the necessary explanations, 100 mg oral sage extract tablets were prescribed daily for the intervention group and placebo for the control group.

Main outcome variables
Quality of life, serum lipids

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140622018187N12**
Registration date: **2020-08-17, 1399/05/27**
Registration timing: **retrospective**

Last update: **2020-08-17, 1399/05/27**
Update count: **0**

Registration date
2020-08-17, 1399/05/27

Registrant information

Name
Sedighe Forouhari

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 987136474257

Email address
foruharis@sums.ac.ir

Recruitment status
Recruitment complete

Funding source
Vice chancellor for research Shiraz University of Medical Sciences

Expected recruitment start date
2014-05-22, 1393/03/01

Expected recruitment end date
2014-06-22, 1393/04/01

Actual recruitment start date
2014-05-22, 1393/03/01

Actual recruitment end date
2014-06-22, 1393/04/01

Trial completion date
2014-06-22, 1393/04/01

Scientific title

Effect of Salvia officinalis Tablet on lipid profile and quality of life in postmenopausal women

Public title

The effect of Salvia officinalis on lipid profile and quality of life in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 45 and 60 years Menstruation in the past year Conscious written consent No known physical or mental illness Do not take any hormonal medications to reduce menopausal symptoms in the past month Do not take lipid-lowering drugs BMI below 29 No history of allergy to herbal medicines No smoking, hookah or drug addiction

Exclusion criteria:

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **102**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The population of eligible women is randomly assigned to two groups using a random permutation block design. The groups are placed and if the numbers 5 to 9 are observed, two people are placed in two groups as BA permutations and we repeat this until we have 51 people in each group. Thus, the samples are divided into two groups A (drug group A) and group B (group consuming drug B) are divided. Women are also informed that they will be accidentally placed in one of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study and the patient and the researcher are not aware of receiving sage and placebo, and both are prepared by the Faculty of Pharmacy and will be provided to the patient with a code. After completing the research, the type of intervention will be determined with codes.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Shiraz University of Medical Sciences

Street address

Research Deputy, Shiraz University of Medical Science shiraz

City

Shiraz

Province

Fars

Postal code

1978-71345

Approval date

2014-03-19, 1392/12/28

Ethics committee reference number

93-01-50-7632

Health conditions studied

1

Description of health condition studied

Menopausal and femal climacteric state

ICD-10 code

N95.1

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

cholesterol

Timepoint

1 week before the intervention and 8 weeks after intervention

Method of measurement

Laboratory

2

Description

Triglycerides

Timepoint

1 week before the intervention and 8 weeks after intervention

Method of measurement

Laboratory

3

Description

HDL

Timepoint

1 week before the intervention and 8 weeks after intervention

Method of measurement

Laboratory

4

Description

LDL

Timepoint

1 week before the intervention and 8 weeks after intervention

Method of measurement

Laboratory

Secondary outcomes

1

Description

Menopause Quality Of Life

Timepoint

1 week before the intervention and 8 weeks after intervention

Method of measurement

Menopause Quality Of Life Questionnaire

Intervention groups

1

Description

Salvia officinalis extract, 100 mg tablet, three times daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Placebo, tablets 100 mg, three times daily, 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari Clinic in Shiraz, Namazi Square, Shiraz

Full name of responsible person

Sedighe Foruhari

Street address

College Of Nursing Midwifery, Shiraz

City

Shiraz

Province

Fars

Postal code

71345-1978

Phone

+98 71 1647 4257

Email

forouharism@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seyed Basir Hashemi

Street address

Technology and Research Office, Research Deputy , Shiraz University of Medical Science, Zand Street, Shiraz

City

Shiraz

Province

Fars

Postal code

71348-14336

Phone

+98 71 3230 5410

Email

president@sums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Sedighe Forouhari

Position

Ph.D , Supervisor

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

Street address
College Of Nursing Midwifery, Shiraz
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3647 4257
Fax
Email
forouharism@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sedighe Forouhari
Position
Ph.D , Supervisor
Latest degree
Ph.D.
Other areas of specialty/work
Gynecology and Obstetrics
Street address
College Of Nursing Midwifery, Shiraz
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 3647 4257
Fax
Email
foruharis@sums.ac
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Sedighe Foruhari
Position
Ph.D , Supervisor
Latest degree
Ph.D.
Other areas of specialty/work
Gynecology and Obstetrics
Street address
College Of Nursing Midwifery, Shiraz
City
Shiraz
Province
Fars
Postal code
71345-1978
Phone
+98 71 1647 4257
Fax
Email
forouharism@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available