Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Salvia officinalis Tablet on hot flash, night sweating and estradiol hormone in postmenopausal women

Protocol summary

Summary

This study aims to investigate the influence of Salvia tablets on hot flashes, night sweats and the estradiol hormone in postmenopausal women who refer to health Care centers in Shiraz in 1393. This study is based on a double-blind randomized clinical trial performed on 100 postmenopausal women with hot flashes who qualified for the study. The population of eligible women is divided into two groups, A and B, each of which consists of 50 patients using Randomized block permutation. Members of group A take medicine A and members of group B take medicine B. Women are well aware that they are divided randomly. The researcher make questionnaire including demographic information and Menopause Rating Scale (MRS) which will be answered by the researcher. The level of concentration of samples of plasma estradiol hormone are controlled. Women are asked to complete the questionnaire , the first week before intervention that includes the number, severity and duration of hot flashes and the number and severity of night sweats. Then they receive three oral tablet (100mg) Sage or placebo per day for 8 weeks and continue filling the forms every week. .At the end of 8 weeks, menopause rating scale questionnaire will be completed by researcher and Estradiol tests will be repeated. The data before and after the intervention will be compared and statically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062218187N1**
Registration date: **2014-07-22, 1393/04/31**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-07-22, 1393/04/31

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

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

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Salvia officinalis Tablet on hot flash, night sweating and estradiol hormone in postmenopausal women

Public title

The effect of Salvia officinalis on hot flush and night sweat in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women between 45 to 60 years old who are less than 5 years after menopause; At least 12 months since last menstruation; At least three hot flushes daily; Written informed consent; No known physical or mental illness; Not using any medication with influence on menopausal symptoms within three month before the study start; BMI less than 29; No history of allergy to herbal medicine; No smoking or addiction; No use of medication with influence on menopausal symptoms. Exclusion criteria:Use of medication with influence on menopausal symptoms; Allergy to the medicine used or not used in the study; Patient reluctance

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Ethics Committee, Shiraz University of Medical Sciences

Street address
Research Deputy, Shiraz University of Medical Science

City
shiraz

Postal code
1978-71345

Approval date
2014-03-19, 1392/12/28

Ethics committee reference number
92-6942

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
hot flash

Timepoint
1 week before the intervention and 8 weeks after intervention

Method of measurement
Questionnaire

2

Description
Night sweats

Timepoint
1 week before the intervention and 8 weeks after intervention

Method of measurement
Questionnaire

3

Description
Estradiol

Timepoint
1 week before the intervention and 8 weeks after intervention

Method of measurement
Laboratory pg per ml

Secondary outcomes

1

Description
Menopausal Symptoms

Timepoint
1 week before the intervention and 8 weeks after intervention

Method of measurement
Menopause Rating Scale 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
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Motahari Clinic in Shiraz
Full name of responsible person
Sima Gichlou, Studend of Msc in Midwifery
Street address
City
tehran

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
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
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
Shiraz University of Medical Sciences
Full name of responsible person
Sedighe Forouhari
Position
Master Of Midwifery, Guide Master
Other areas of specialty/work
Street address
College Of Nursing Midwifery, Shiraz
City
shiraz
Postal code
71345-1978
Phone
+98 71 1647 4257
Fax
+98 71 1647 4252
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
Master Of Midwifery, Guide Master
Other areas of specialty/work
Street address
College Of Nursing Midwifery, Shiraz
City
shiraz
Postal code
71345-1978
Phone
+98 71 1647 4257
Fax
+98 71 1647 4252
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 Forouhari
Position
Master Of Midwifery, Guide Master
Other areas of specialty/work
Street address
College Of Nursing Midwifery, Shiraz
City
shiraz
Postal code
Phone
+98 71 1647 4257
Fax
+98 71 1647 4252
Email
forouharism@yahoo.com

Web page address

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