

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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)

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+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, Student 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

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Web page address

empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Data Dictionary

Statistical Analysis Plan

empty