

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

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

Protocol summary

Summary

The aim of this triple blind randomized placebo controlled trial, is to investigate effect of *Salvia officinalis* on hot flush and sweating in menopausal women who refer to clinic by this complains. Participants consist of 84 women by this inclusion criteria: menopause age 45-60, at least 12 month since last menstruation, no serious illnesses, no use of HRT, BMI below 29, no stress at least during last month. no allergy to herb or plants, normal diet, no smoking or addiction. Exclusion criteria include the use of medication with influence on menopausal symptoms, allergy to Sage or not using Sage. They randomly divide into group A (will receive one A capsule daily) and group B (will receive one B capsule daily). At first participants will be asked to fill some forms about their hot flush, the severity, duration and frequency of their hot flush and severity and frequency of sweating in one week before intervention. Then they will receive one oral capsule (100mg) Sage or placebo in 8 weeks and continue filling the forms every week. The data before and after intervention will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012070410182N1**

Registration date: **2013-01-03, 1391/10/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-03, 1391/10/14

Registrant information

Name

Homa Sadeghi Avval Shahr

Name of organization / entity

Tehran University of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6692 7171

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-08-28, 1391/06/07

Expected recruitment end date

2012-11-04, 1391/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

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

Public title

Effects of Sage on hot flush and sweat in menopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 45-60 (in 60 years we include women that maximum 5 year); married; by history of maternity; at least 12 month since last menstruation; ability to read and write; at least 3 hot flushes daily; no serious illnesses; no smoking or addict; no use of HRT; BMI < 29; no stress at least 1 month; normal food; no

allergy to herb or plants. Exclusion criteria: no inclination for using of drug; no filling the forms; use of medication with an influence on menopausal symptoms; in stress or use of special food diet; allergy to drug.

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: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences, Faculty of Nursing and Midwifery

Street address

Faculty of Nursing and Midwifery, Tohid square, Tehran

City

Tehran

Postal code

1419733171

Approval date

2012-07-29, 1391/05/08

Ethics committee reference number

907/130/91/5

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

Hotflush

Timepoint

1 week before intervention, 8 week after intervention

Method of measurement

questionnaire

2

Description

Sweat

Timepoint

1 week before intervention, 8 week after intervention

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Extract of Salvia officinalis- Capsul 100 mg- Oral- Daily- 8 week

Category

Treatment - Drugs

2

Description

Placebo- Capsul 100 mgr- Daily- 8 week

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Lahijan number 1 the health and curative center

Full name of responsible person

Mahnaz Bakhshi, Studend of Msc in Midwifery

Street address

Lahijan number 1 the health and curative center, 22 aban street, Lahijan

City

Lahijan

Sponsors / Funding sources

1

Sponsor

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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

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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