

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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

##### Email address

ho-sadeghi@tums.ac.ir

##### 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

907/130/91/۵

## 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

**Name of organization / entity**

Tehran University of Medical Sciences  
**Full name of responsible person**  
Homa Sadeghi, Msc in midwifery  
**Street address**  
Faculty of Nursing and Midwifery, Tohid Square,  
Tehran  
**City**  
Tehran  
**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

**Contact**  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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*