

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparative of the effect of combination of black Kohush - soybean and Primerose oil versus placebo on hot flash and night sweating in menopausal women: a double blind randomized clinical trial

#### Protocol summary

##### Study aim

To assess the effect of combination of black Kohush - soybean and Primerose oil versus placebo on hot flash and night sweating in menopausal women

##### Design

This a double-blind randomized clinical trial, phase II, in which 120 eligible menopausal women will be randomly assigned to the intervention and control groups

##### Settings and conduct

The eligible menopausal women who will refer to Health Centers in Hamadan City during the study period will be enrolled in the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 45 to 80 years Menopause  
Exclusion criteria: Any acute or chronic disease Using any herbal drug during the past e months  
Hypersensitivity to medicinal pants

##### Intervention groups

Intervention group 1: Oral using a combination of black Kohush - soybean twice a day for 8 weeks  
Intervention group 2: Using Primerose oil capsule twice a day for 8 weeks  
Control group: Using placebo twice a day for 8 weeks

##### Main outcome variables

Primary outcome: Assessing hot flash before intervention and 8 weeks after that using standard questionnaire  
Assessing night sweating before intervention and 8 weeks after that by history taking

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N210**  
Registration date: **2018-03-11, 1396/12/20**  
Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-11, 1396/12/20**

Update count: **0**

##### Registration date

2018-03-11, 1396/12/20

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-03-11, 1396/12/20

##### Expected recruitment end date

2019-03-11, 1397/12/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative of the effect of combination of black Kohush - soybean and Primerose oil versus placebo on hot flash and night sweating in menopausal women: a double blind randomized clinical trial

##### Public title

Comparative of the effect of combination of black Kohush - soybean and Primerose oil versus placebo on hot flash and night sweating in menopausal women

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Age of 45 to 80 years Menopause

##### **Exclusion criteria:**

Any acute or chronic disease Using any herbal drug during the past e months Hypersensitivity to medicinal pants

#### **Age**

From **45 years** old to **80 years** old

#### **Gender**

Female

#### **Phase**

2

#### **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

#### **Sample size**

Target sample size: **120**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

Random assignment of the patients to the intervention and control groups through drawing of lots

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double-blind

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

###### **Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

###### **City**

hamadan

#### **Province**

Hamadan

#### **Postal code**

6517838695

#### **Approval date**

2018-02-24, 1396/12/05

#### **Ethics committee reference number**

IR.UMSHA.REC.1396.822

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Menopaus

##### **ICD-10 code**

N95.1

##### **ICD-10 code description**

Menopausal and female climacteric states

### **Primary outcomes**

#### **1**

##### **Description**

Assessing hot flash

##### **Timepoint**

Before intervention and 8 weeks after that

##### **Method of measurement**

Using standard questionnaire

#### **2**

##### **Description**

Assessing night sweating

##### **Timepoint**

Before intervention and 8 weeks after that

##### **Method of measurement**

By history taking

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group 1: Oral using a combination of black Kohush - soybean twice a day for 8 weeks

##### **Category**

Treatment - Drugs

#### **2**

##### **Description**

Intervention group 2: Using Primerose oil capsule twice a day for 8 weeks

##### **Category**

Treatment - Drugs

### 3

#### Description

Control group: Using placebo twice a day for 8 weeks

#### Category

Placebo

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Health Centers in Hamadan City

###### Full name of responsible person

Dr. Seyyedeh Zahra Masoomi

###### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

###### City

Hamadan

###### Province

Hamadan

###### Postal code

6517838695

###### Phone

+98 81 3838 0572

###### Email

zahramid2001@yahoo.com

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Hamedan University of Medical Sciences

###### Full name of responsible person

Dr Saeid Bashirian

###### Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Ave

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info.research@umsha.ac.ir

###### Grant name

###### Grant code / Reference number

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

Yes

###### Title of funding source

Hamedan 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

Hamedan University of Medical Sciences

###### Full name of responsible person

Dr. Seyyedeh Zahra Masoomi

###### Position

Fertility Health

###### Latest degree

Ph.D.

###### Other areas of specialty/work

Midwifery

###### Street address

School of Nursing and Midwifery, Hamadan University of Medical Sciences, Shahid Fahmideh Ave.

###### City

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###### Province

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###### Phone

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### Person responsible for scientific inquiries

##### Contact

###### Name of organization / entity

Hamedan University of Medical Sciences

###### Full name of responsible person

Dr. Seyyedeh Zahra Masoomi

###### Position

Fertility Health

###### Latest degree

Ph.D.

###### Other areas of specialty/work

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Professor of Epidemiology

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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**Province**

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### Email

poorolajal@umsha.ac.ir

## 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