

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Comparative evaluation of Cimifugol and Salvigol effect on hot flash ,night sweating in menopausal women

#### Protocol summary

##### Summary

Objectives: The goal of this clinical trial study is to compare the effect of Cimifugol and Salvigol on menopausal symptoms (hot flashes, night sweating). Inclusion and criteria: Menopause women with at least one year after amenorrhea history that suffer from menopausal symptoms. Exclusion criteria: a history of malignancies in the past or right now; having active hepatic or renal disease; taking androgen, progesterone, HRT or other treatments to relief menopausal symptoms. Study population and sample size: 80 menopause women from Hamadan. Intervention: After explaining goal of the study to participants and obtaining informed consent, information about menopause will be recorded and Green's menopausal index will be used to assess the severity of menopausal symptoms. Samples will be divided randomly in two groups; one will take Cimifugol and another one Salvigol Balance for 8 weeks. At the end of every week, we will call samples to make sure of using drugs. Green's menopausal index will be completed again at the end of 4th and 8th weeks, and two groups will be compared. Findings will be analyzed by SPSS software. Primary outcomes: Relieving menopausal symptoms.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016070723640N5**  
Registration date: **2016-09-04, 1395/06/14**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-09-04, 1395/06/14

#### Registrant information

##### Name

Farzaneh Soltani

##### Name of organization / entity

Hamedan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 813220683

##### Email address

soltani@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Research deputy of Hamadan University of Medical sciences

#### Expected recruitment start date

2016-04-08, 1395/01/20

#### Expected recruitment end date

2016-09-10, 1395/06/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparative evaluation of Cimifugol and Salvigol effect on hot flash ,night sweating in menopausal women

#### Public title

Comparative evaluation of Cimifugol and Salvigol effect on hot flash ,night sweating in menopausal women attending to Hamadan health care centers in 2016

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: At least one year after the last amenorrhea; lack of acute and chronic diseases with the

approval of physician; not taking any herbal remedy from 3 months before the intervention; no previous allergy to herbal drugs. Exclusion criteria: having breast and genital cancer or a history of having them in the past; experiencing acute and chronic diseases during the study; lack of proper use of drugs during the study; medical allergy.

**Age**

From **40 years** old to **60 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not 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**

Fahmih Street, Hamadan University of Medical Sciences, Department of Research and Technology

**City**

Hamadan

**Postal code**

65178/518

**Approval date**

2016-02-27, 1394/12/08

**Ethics committee reference number**

IR.UMSHA.REC.1394.532

**Health conditions studied****1****Description of health condition studied**

Symptoms of Menopause

**ICD-10 code**

N95.1

**ICD-10 code description**

Menopausal and female climacteric states

**Primary outcomes****1****Description**

Hot flash

**Timepoint**

before intervention- 4 weeks later- 8 weeks later

**Method of measurement**

Scale Greene

**2****Description**

night sweating

**Timepoint**

before intervention- 4 weeks later- 8 weeks later

**Method of measurement**

Scale Greene

**Secondary outcomes****1****Description**

side effects

**Timepoint**

End of every week by calling.

**Method of measurement**

End of every week by calling.

**Intervention groups****1****Description**

first group: They will use oral tablet Cimi fugol daily for 8 weeks ,one tablet after dinner.

**Category**

Treatment - Drugs

**2****Description**

second group: Salvia officinalis extract, 100 mg tablet, three times daily for 8 weeks.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shohada Medical and Health Center

**Full name of responsible person**

Roya Ahmadi Niyatabesh, M.Sc. of Health, Instructor

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No. 11, Takhti Street, Shohada Medical and Health Center, Hamadan

**City**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Hamadan University of Medical Sciences

**Full name of responsible person**

Farzaneh Soltani

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PhD in Reproductive Health

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Hamadan University of Medical Sciences

**Full name of responsible person**

Dr. Bashirian Saeed

**Street address**

Fahmiheh Street, Hamadan University of Medical Sciences, Hamadan

**City**

Hamadan

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

Yes

**Title of funding source**

Vice chancellor for research, Hamadan 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**

Hamadan University of Medical Sciences

**Full name of responsible person**

Roya Ahmadi Niyatabesh

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Student Counseling in Midwifery

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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*