Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparative evalution 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

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Iran (Islamic Republic of)

Phone

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

Public title

Comparative evalution 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
Fahmiheh 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
firct 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

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

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

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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