Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
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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
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
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Person responsible for updating data

Contact

Name of organization / entity
Hamedan University of Medical Sciences

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Dr Jalal Poorolajal

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Professor of Epidemiology

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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