Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of green basil (Ocimum basilicum) leaf powder versus placebo on menopausal rating scale and sleep quality in postmenopausal women: a triple-blind randomized clinical trial

Protocol summary

Study aim
To assess the effect of green basil (Ocimum basilicum) leaf powder versus placebo on menopausal rating scale and sleep quality in postmenopausal women

Design
This is a Phase III triple-blind randomized clinical trial with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using computer.

Settings and conduct
This study will be conducted at the Comprehensive Health Centers in Hamadan city, involving 76 eligible postmenopausal women. The patients will be randomly assigned to the intervention and control groups using computer. This trial will be triple-blinded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 45 to 55 years At least 1 to 5 years after menopause Poor sleep quality Exclusion criteria: Smoking or alcohol use Hormone therapy Use of sedatives or sleeping pills

Intervention groups
Intervention group: Routine menopausal care plus capsules containing green basil powder 450 mg twice daily for 28 days Control group: Routine menopausal care plus capsules containing placebo (starch) twice daily for 28 days

Main outcome variables
Primary outcome: Sleep quality Menopause symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120215009014N542**
Registration date: **2024-11-28, 1403/09/08**
Registration timing: **prospective**
Last update: **2024-12-27, 1403/10/07**
Update count: **1**

Registration date
2024-11-28, 1403/09/08

Registrant information
Name
Jalal Poorolajal
Name of organization / entity
Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-12-21, 1403/10/01

Expected recruitment end date
2025-03-05, 1403/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of green basil (Ocimum basilicum) leaf powder versus placebo on menopausal rating scale and sleep quality in postmenopausal women: a triple-blind randomized clinical trial

Public title

Effect of green basil (Ocimum basilicum) leaf powder versus placebo on menopausal rating scale and sleep quality in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 45 to 55 years At least 1 to 5 years after menopause Poor sleep quality

Exclusion criteria:

Smoking or alcohol use Hormone therapy Use of sedatives or sleeping pills

Age

From **44 years** old to **55 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to intervention and control groups using computer generated numbers. For this purpose, we receive a number from the computer when each patient visits, if the number is odd, the patient is assigned to the intervention group, and if the number is even, to the control group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. The analyzer responsible for evaluating the trial's results will also be kept blind to the type of interventions. Therefore, the trial will be conducted as a triple-blind study.

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, Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2024-11-02, 1403/08/12

Ethics committee reference number

IR.UMSHA.REC.1403.550

Health conditions studied

1

Description of health condition studied

Perimenopausal disorders

ICD-10 code

N95

ICD-10 code description

Menopausal and other perimenopausal disorders

Primary outcomes

1

Description

Sleep quality

Timepoint

Before intervention and 28 days later

Method of measurement

Using the Pittsburgh Sleep Quality Questionnaire

2

Description

Menopause symptoms

Timepoint

Before intervention and 28 days later

Method of measurement

Using the Menopause Rating Scale (MRS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine menopausal care plus

capsules containing green basil powder 450 mg twice daily for 28 days

Category

Treatment - Drugs

2

Description

Control group:Routine menopausal care plus capsules containing placebo (starch) twice daily for 28 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Centers in Hamadan city

Full name of responsible person

Nastaran Barati

Street address

School of Pharmacy, Hamadan University of Medical Sciences, 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

Nastaran Barati

Position

Biotechnology Student

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biotechnology

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Person responsible for updating data

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Full name of responsible person

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Position

Professor of Epidemiology

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Other areas of specialty/work

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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