Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Cinnamon and Saffron on menopause symptoms and fatigue among menopausal women

Protocol summary

Study aim
Determining the effect of a combination of saffron and cinnamon on the severity of menopausal symptoms and fatigue in postmenopausal women

Design
A phase II randomized, double-blind, parallel-group, controlled clinical trial was conducted on 64 participants. Randomization was performed using the RAND function in Microsoft Excel

Settings and conduct
Participants are randomly assigned to the two groups of 32 recipients of capsule of cinnamon-saffron extract and placebo group.This study will be conducted in Comprehensive Health Centers of Hamadan city. In this study, neither the researcher nor the menopausal women knows the contents of the package and double blinded will be performed. In intervention group, Capsule of cinnamon-saffron extract and in Control group, placebo will be prescribed Twice in a day along two months.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 45-55 years, at least 1 year after menopause (12 months after cessation of menstruation), no smoking or alcohol consumption, no mental or physical illness, no use of relaxation techniques, no use of herbal and hormonal treatments at least 3 months before the intervention Exclusion criteria: Failure to complete the course of treatment

Intervention groups
Intervention group: Capsule of cinnamon-saffron extract will be prescribed in the form of Oral Capsule 1000 mg, once a day for 6 weeks. This drug will be produced by Hamadan University of Medical Sciences. Control group: placebo will be prescribed in the form of Oral Capsule contain of Starch 1000 mg once a day for 6 weeks. Placebo is made by Hamadan University of Medical Sciences.

Main outcome variables
Menopausal symptoms; fatigue

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120821010635N4**
Registration date: **2026-02-07, 1404/11/18**
Registration timing: **prospective**

Last update: **2026-02-07, 1404/11/18**
Update count: **0**

Registration date
2026-02-07, 1404/11/18

Registrant information

Name
Soodabeh Aghababaei

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3838 0150

Email address
aghababaii@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2026-03-01, 1404/12/10

Expected recruitment end date
2026-08-01, 1405/05/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of Cinnamon and Saffron on menopause symptoms and fatigue among menopausal women

Public title
The effect of Cinnamon and Saffron on menopause symptoms and fatigue among menopausal women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 45-55 years At least 1 year after menopause (12 months after cessation of menstruation) No smoking or alcohol consumption No physical or mental illness No use of relaxation techniques No use of herbal and hormonal treatments at least 3 months before the intervention
Exclusion criteria:
Failure to complete the course of treatment
Age
From **45 years** old to **55 years** old
Gender
Female

Phase
2
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants are randomly selected by (rand between (1; 2)) command, in the Excel computer program that are assigned to the two groups of 32 recipients of capsule of Cinnamon-Saffron extract and placebo.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drug packages are similar and were given to menopausal women by other person. This person does not inform about the package contents. therefore, neither the researcher nor the menopausal women knows the contents of the package and double blinding will be performed.
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
Hamadan Uiniversity of medical sciences, Shahid Fahmideh Ave, Hamadan
City
Hamadan
Province
Hamadan
Postal code
۶۵۱۷۸۳۸۶۹۸
Approval date
2026-01-24, 1404/11/04
Ethics committee reference number
IR.UMSHA.REC.1404.895

Health conditions studied

1

Description of health condition studied
Hot flashes
ICD-10 code
N95.1
ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Menopausal symptoms
Timepoint
Before the start of the intervention, 3 weeks and 6 weeks after the end of the intervention
Method of measurement
Menopausal Rating Score

Secondary outcomes

1

Description
Fatigue
Timepoint
Before the start of the intervention, 3 and 6 weeks after the end of the intervention
Method of measurement
Fatigue Severity Scale

Intervention groups

1

Description
Intervention group: Capsule of Cinnamon-Saffron extract will be prescribed in the form of Oral Capsule 1000 mg, once a day for 6 weeks. Hamadan University of Medical Sciences will produce this drug.
Category

Treatment - Drugs

2

Description
Control group: Placebo will be prescribed in the form of an oral capsule containing starch 1000 mg, once a day, for 6 weeks. The placebo is made in Hamadan University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Khomini Health center
Full name of responsible person
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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
Soodabeh Aghababaei
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Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
Not applicable

Title and more details about the data/document
Information about the main outcome

When the data will become available and for how long
6 months after printing the results

To whom data/document is available
Researchers working in academia

Under which criteria data/document could be used
Data analysis is permitted with the author's permission.

From where data/document is obtainable
Hamadan University of Medical Sciences

What processes are involved for a request to access data/document
6 months after of paper publish

Comments
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