

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of cinnamon capsule on the severity of menopausal symptoms in women covered by comprehensive health centers in Hamadan in 2021

Protocol summary

Study aim

Determining the effect of cinnamon capsule on the severity of menopausal symptoms

Design

This is a randomized clinical trial study in which 60 eligible individuals will be randomly assigned to the intervention and control groups.

Settings and conduct

Eligible women who refer to the comprehensive health centers of Hamadancity during the study will be randomly assigned to intervention and control groups.

Participants/Inclusion and exclusion criteria

Age range 45 to 60 years, At least one year and at most 3 years have passed since the last menstrual period, Menopause naturally, Score 12 or higher on the Menopause Symptoms Scale

Intervention groups

Intervention group: Cinnamon capsules, once a day, for 2 months
Control group: taking a placebo once a day for 2 months

Main outcome variables

Severity of menopausal symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200530047596N2**

Registration date: **2021-03-02, 1399/12/12**

Registration timing: **prospective**

Last update: **2021-03-02, 1399/12/12**

Update count: **0**

Registration date

2021-03-02, 1399/12/12

Registrant information

Name

Mansoureh Refaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0150

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-19, 1400/01/30

Expected recruitment end date

2021-10-22, 1400/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cinnamon capsule on the severity of menopausal symptoms in women covered by comprehensive health centers in Hamadan in 2021

Public title

The effect of cinnamon on menopausal symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 45 to 60 years At least one year and at most 3 years have passed since the last menstrual period
Menopause naturally Score 12 or higher on the Menopause Symptoms Scale

Exclusion criteria:

receiving hormone therapy history of hysterectomy or

oophorectomy medical or psychological problems Take any herbal or chemical medicine

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The sequence of random allocation will be determined by one of the researchers based on the permutation blocking method in two groups A and B, using RAS(Random allocation software) software. the determined sequence will be numbered from number one to 60 from beginning to end, respectively. Capsules (cinnamon and placebo) are placed in 60 pieces in similar sealed and opaque envelopes. Then, each number envelope is assigned to the number of samples, ie from 1 to 60. Therefore, only the researcher who made the random assignment knows what drug each envelope contains. The numbered envelopes are then given to another researcher who is unaware of the random allocation process. Then the samples are received in order and the number of envelopes is received, the medicine is received and the envelope number is stated in the questionnaire. Participants will not be informed of the type of group assigned. After collecting the data, the data is entered into the software based on the numbers and groups A and B, and thus the statistical analyst will not be aware of the type of group assigned.

Blinding (investigator's opinion)

Double blinded

Blinding description

First, 60 envelopes with the same matte shape are prepared. Cinnamon capsules in 30 packs and starch capsules in 30 packs. Due to the uniform shape and uniform consumption of the capsules, participants will not be aware of the type of substance used. On the other hand, the envelopes will be numbered according to the specified sequence from 1 to 60 and will be given to the participants by a researcher who does not know the sequence. The same researcher will then evaluate the consequences. On the other hand, the statistical analyzer will not be aware of the type of intervention groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Ethic Committee of Hamadan University of Medical Sciences

Street address

Shahid Fahmideh

City

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Province

Hamadan

Postal code

6517838698

Approval date

2021-02-27, 1399/12/09

Ethics committee reference number

IR.UMSHA.REC.1399.1012

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

Menopausal symptoms

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

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

The severity of menopausal symptoms

Timepoint

Before the intervention and 2 months after taking the capsules

Method of measurement

Menopause Rating Scale

Secondary outcomes

empty

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

Intervention group: Participants are asked to consume one capsule containing one gram of cinnamon powder daily, which is prepared in the Faculty of Pharmacy of Hamadan University of Medical Sciences, for 2 months.

Category

Treatment - Other

2

Description

Control group: Participants are asked to consume one capsule containing one gram of starch powder daily, which is prepared in the Faculty of Pharmacy of Hamadan University of Medical Sciences, for 2 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive centers of Hamedan

Full name of responsible person

Mansoureh Refaei

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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

Mansoureh Refaei

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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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