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 comperhensive 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

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Mansoureh Refaei
Name of organization / entity
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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 comperhensive 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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Hamadan

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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
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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
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Mansoureh Refaei
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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