Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Green tea tablet on the severity of Menopausal Symptoms in Postmenopausal women

Protocol summary

Study aim
The effect of Green tea tablet on severity of the menopausal symptoms of the menopausal women

Design
Clinical trial with control group, with parallel groups, triple blind, randomized

Settings and conduct
Participants in this study were randomly assigned to two groups of 45 individuals each: one group received green tea pills, while the other group received a placebo. The study will take place at comprehensive health service centers in Hamedan. To ensure unbiased results, neither the researcher, the postmenopausal women involved, nor the analyst will know the contents of the packages; this process is referred to as triple blinding. The intervention group will receive the green tea pills, while the control group will receive the placebo, both administered twice a day for a duration of 6 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 45-55, having menopause symptoms; not using cigarette or alcohol, not having physical or mental diseases, not using of relaxation techniques, not using of hormonal or herbal therapies
Exclusion criteria: irregular use of the drug, refuse from continuing to participate in study

Intervention groups
Intervention group: The intervention group will take two 450 mg green tea tablets (produced by Dineh Company) daily, at least half an hour after each meal (breakfast and dinner), for six weeks. Control group: Participants will take two 450 mg placebo tablets daily for 6 weeks, similar to the intervention group.

Main outcome variables
Severity of menopause symptoms

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180707040370N12**
Registration date: **2025-03-10, 1403/12/20**
Registration timing: **prospective**

Last update: **2025-03-10, 1403/12/20**
Update count: **0**

Registration date
2025-03-10, 1403/12/20

Registrant information

Name
Ensiyeh Jenabi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 81 3838 0496

Email address
e.jenabi@umsha.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-10, 1404/02/20

Expected recruitment end date
2026-01-10, 1404/10/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Green tea tablet on the severity of Menopausal Symptoms in Postmenopausal women

Public title

The effect of Green tea tablet on the severity of Menopausal Symptoms

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

age between 45-55 at least 1 to 5 years have passed since menopause Being married and leading a stable life with your spouse.

Exclusion criteria:

Acute and chronic illnesses observed during the study. Allergy to green tea supplements. Using cigarette or alcohol Taking any herbal or hormonal medications for three months before the intervention. Prior allergies to medical plants

Age

From **45 years** old to **55 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are randomly selected by random.org computer program that are assigned to the two groups of 45 recipients of Green tea tablet and placebo. The allocation of the participants to the groups is performed by method of allocation concealment. In this way, using the random block 4, the allocation sequence is specified. Then, in the sealed envelopes, the intervention name is written in sequential order, and is numbered accordingly

Blinding (investigator's opinion)

Triple 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 and nor the analyzer knows the contents of the package and triple 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 University of Medical Sciences, Fahmiheh Street, Hamadan

City

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Province

Hamadan

Postal code

6517838678

Approval date

2025-03-01, 1403/12/11

Ethics committee reference number

IR.UMSHA.REC.1403.878

Health conditions studied

1

Description of health condition studied

Severity of the Menopausal Symptoms

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

Primary outcomes

1

Description

Severity of menopause symptoms

Timepoint

Before the intervention, 3 and 6 weeks after the intervention

Method of measurement

MRS scale

Secondary outcomes

1

Description

Stress

Timepoint

Before the intervention, 3 and 6 weeks after the intervention

Method of measurement

Questionnaire DASS-21

2

Description

anxiety

Timepoint

Before the intervention, 3 and 6 weeks after the intervention

Method of measurement
Questionnaire DASS-21

3

Description
depression
Timepoint
Before the intervention, 3 and 6 weeks after the intervention
Method of measurement
Questionnaire DASS-21

Intervention groups

1

Description
Intervention group: The intervention group will take two 450 mg green tea tablets (produced by Dineh Company) daily, at least half an hour after each meal (breakfast and dinner), for six weeks.
Category
Treatment - Drugs

2

Description
Control group: Participants will take two 450 mg placebo tablets daily for 6 weeks, similar to the intervention group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Comprehensive Health Service Center of Shohada
Full name of responsible person
Ensiyeh Jenabi
Street address
Comprehensive Health Service Center of Shohada., Takhti Ave., Hamadan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Alireza soltanian
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Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Av
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arsoltanian@yahoo.com
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
Ensiyeh Jenabi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
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Person responsible for scientific inquiries

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Ph.D.

Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

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

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
No - There is not 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
A portion of the information, such as information on the main outcome or the like, can be shared

When the data will become available and for how long
6 months after publishing 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 ،Vice-chancellor for Research, Hamadan University of Medical Sciences, Shahid Fahmideh Ave Responsible person: Ensiyeh Jenabi Postal code: 6517838695 Phone number: +98 81 3838 0496 Email: en.jenabi@yahoo.com

What processes are involved for a request to access data/document
Requests should be submitted to the corresponding author via email. He will follow up with the inquiry

Comments