Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of oral lavender essential oil on menopausal symptoms, serum lipid profile, and cortisol concentration in postmenopausal women: A triple-blind, randomized, controlled trial

Protocol summary

Study aim
The effect of oral lavender essential oil on menopausal symptoms, serum lipid profile, and cortisol concentration in postmenopausal women:

Design
The controlled clinical trial, with two parallel arms, triple-blind, randomized, phase 3 on 72 patients. Random Allocation Software will be used for randomization

Settings and conduct
The eligible postmenopausal women referring to the Tabriz health centers will be selected through convenience sampling. Participants will be randomly assigned to two groups of consumers of gelatin capsules containing lavender and placebo using a random blocking method with a 1: 1 allocation ratio. The researcher, participant, data analyst, and outcome assessor will be blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women who spent less than 6 years old after menopause and get a score of 15 to 42 from the Green assessment. Exclusion criteria: Lavender consumption during the last 3 months, hormone therapy during the last 6 months, presence of a serious illness

Intervention groups
The first group will receive one 80 mg gelatin capsule per day containing lavender essential oil for 60 days. The second group will receive one 80 mg placebo capsule per day similar to the first group. The placebo will be taken with the same prescription as the lavender capsule.

Main outcome variables
Changes in mean of Green scale score, serum lipid profile levels, and serum cortisol levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131009014957N13**
Registration date: **2022-04-27, 1401/02/07**
Registration timing: **prospective**

Last update: **2022-04-27, 1401/02/07**
Update count: **0**

Registration date
2022-04-27, 1401/02/07

Registrant information

Name
Azizeh Farshbaf-khalili

Name of organization / entity
Tabriz 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
2022-05-10, 1401/02/20

Expected recruitment end date
2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of oral lavender essential oil on menopausal

symptoms, serum lipid profile, and cortisol concentration in postmenopausal women: A triple-blind, randomized, controlled trial

Public title
The effect of oral lavender essential oil on menopausal symptoms, serum lipid profile, and cortisol concentration in postmenopausal women

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Be literate enough to fill out a questionnaire or presence of a literate person in the family Having a normal menopause Women who were menopause less than 6 years ago Having a minimum of 45 and a maximum of 60 years of age Earning a minimum score of 15 and a maximum of 42 in the Green assessment

Exclusion criteria:
Use of tobacco and alcoholic beverages and herbal medicines Existence of stressors such as the death of first-degree relatives in the last 6 months and job loss Existence of malignant disease Recent history of surgery and trauma Lavender consumption during the 3 months before the study Use of hormone therapy during the past 6 months Having known physical and mental illnesses according to self-expression (depression, uncontrolled diabetes, cardiovascular diseases)

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
Eligible women will be assigned into two groups of Lavender gelatin capsule or placebo using a randomized blocking method with the 4 and 6-sized blocks and a 1: 1 allocation ratio. The allocation sequence will be generated by the researcher through RAS (Random Allocation Software). The medicines and placebo will be placed in a container. Containers will be assigned numbers from 1 to 72. They will be the same shape, closed, opaque, and contain 60 capsules, and their preparation will be done based on the sequence allocation by the person not involved in the research.

Blinding (investigator's opinion)
Triple blinded

Blinding description
The first group will receive one Lavender essential oil 80 mg capsule daily, and the second group will receive a placebo capsule that will be the same shape, color, and weight. participants, the principal investigator, health care personnel, those evaluating the outcome, the Data Safety and Monitoring Committee, and those drafting the article will be blinded

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Tabriz University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Floor 3, No 2 Central Building, Tabriz University of Medical Sciences, Golghasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5165665931

Approval date
2022-02-15, 1400/11/26

Ethics committee reference number
IR.TBZMED.REC.1400.1186

Health conditions studied

1

Description of health condition studied
Menopausal symptoms

ICD-10 code
N95

ICD-10 code description
Menopausal and other perimenopausal disorders

Primary outcomes

1

Description
Green scale symptoms score in postmenopausal women

Timepoint
Before and after intervention

Method of measurement
Green questionnaire

2

Description
Serum cortisol levels
Timepoint
Before and after intervention
Method of measurement
Enzyme-linked immunosorbent assay (ELISA) method by ELISA kits

Secondary outcomes

1

Description
Reported possible side effects
Timepoint
After the intervention
Method of measurement
Checklist of possible side effects

2

Description
The level of satisfaction with the intervention received
Timepoint
After the intervention
Method of measurement
Satisfaction checklist received from the intervention

3

Description
Serum levels of lipid profile
Timepoint
Before and after intervention
Method of measurement
By spectrophotometric method with device with Alcyon 300 model and Pars test kit

Intervention groups

1

Description
Intervention group: Recipient of gelatin capsules containing 80 mg of lavender essential oil. The course of drug consumption is 60 days and one capsule is consumed daily after a meal, which is prepared in 30-number packages by Barij Essential Oil Company and will be delivered to the participants in two periods.
Category
Treatment - Drugs

2

Description
Control group: Recipient of placebo in the form of a gelatin capsule that is very similar in color and weight to a lavender gelatin capsule and will be made by Barij Essential Oil Company, except that it will have no effective substance. The placebo will be given to participants with the same instructions as Lavender Gelatin Capsules.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Public health departments in Tabriz
Full name of responsible person
Dr Mitra Yeghaneh
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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No. 2 Central building of the university, Golgasht street, Azadi street
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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
Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Azizeh Farshbaf-Khalili

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Data on the main outcome will be published

When the data will become available and for how long

Six months after printing the results

To whom data/document is available

Researchers at institutions have access to data

Under which criteria data/document could be used

In order to help scientific progress in the field of research

From where data/document is obtainable

farshbafa@tbzmed.ac.ir Dr. Azizeh Farshbaf Khalili

What processes are involved for a request to access data/document

Scientific approval of the applicant by Tabriz University

of Medical Sciences

Comments