Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of oral capsule curcumin and vitamin E in comparison to placebo on serum levels of some antioxidants and inflammatory factors in postmenopausal women: A randomized, triple-controlled clinical trial.

Protocol summary

Study aim

Determination of the effect of curcumin and vitamin E in comparison with placebo on serum levels of some antioxidants and inflammatory factors in postmenopausal women

Design

En Randomized controlled clinical trial with three parallel arms.

Settings and conduct

This is a randomized, triplicate randomized controlled triplicate study on 93 postmenopausal women in Tabriz.Sampling in three different health centers will be done in terms of socioeconomic status. At before the intervention and after the intervention, after about 12 hours of fasting in the laboratory, the researcher 5 cc blood was taken and in three separate tubes with 3000 rpm in a minute for centrifugation at -70 ° C Centimeters will be kept until the tests are performed, the second time after the intervention, and the Total Antioxidant Capacity TAC, MDA, high sensitivity (hsCRP C-Reactive Protein), TNF-α (Tumor Necrosis Factor. Contributors will be assigned randomized blocking with a 1: 1: 1 assignment ratio to three groups (two intervention groups and one control group).

Participants/Inclusion and exclusion criteria

Participants in postmenopausal women aged 40 to 60 years who score at least 15 and a maximum of 42 in the Green Questionnaire have hot flash symptoms.

Intervention groups

The first intervention group received 500 mg capsicum capsules twice daily for up to eight weeks, the second intervention group received 200 IU of oral Capsules twice daily for eight weeks, and the third group receiving the control group will receive a placebo.

Main outcome variables

1) Mean serum levels of MDA and TAC in postmenopausal women 2) Mean serum levels of hsCRP and TNF-α levels in postmenopausal women 3) Mean score of menopausal symptoms and its subtypes in postmenopausal women

General information

Reason for update

Greetings and Regards Correction of recruitment start date, recruitment end date, and completion of trial. Request the removal of tumor necrosis factor due to the very high cost of this kit (more than the total budget of the project) and the addition of renal and liver function, lipid profile and fasting blood sugar tests with lower cost as a secondary outcome. Serum samples have been frozen at -70 and are ready for testing.

Acronym

IRCT registration information

IRCT registration number: **IRCT20131009014957N6**
Registration date: **2019-02-01, 1397/11/12**
Registration timing: **prospective**

Last update: **2020-05-23, 1399/03/03**
Update count: **1**

Registration date

2019-02-01, 1397/11/12

Registrant information

Name

Azizeh Farshbaf-khalili

Name of organization / entity

Tabriz university of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-02-09, 1397/11/20

Expected recruitment end date
2020-02-09, 1398/11/20

Actual recruitment start date
2019-06-05, 1398/03/15

Actual recruitment end date
2020-04-21, 1399/02/02

Trial completion date
2020-06-04, 1399/03/15

Scientific title
The effect of oral capsule curcumin and vitamin E in comparison to placebo on serum levels of some antioxidants and inflammatory factors in postmenopausal women: A randomized, triple-controlled clinical trial.

Public title
The effect of oral capsule curcumin and vitamin E in comparison to placebo on serum levels of some antioxidants and inflammatory factors in postmenopausal women: A randomized, triple-controlled clinical trial.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1) Readiness to participate in the study 2) Having sufficient literacy to complete the questionnaire or the presence of a literate person in the family 3) has normal menopause 4) Women who are less than 6 years old from their menopause. 5) having at least 40 years and a maximum of 60 6)Earn a minimum score of 15 and a maximum of 42 in the Green AssessmentHot flashes

Exclusion criteria:
1) Use of tobacco and alcohol and herbal medicines 2) Stress factors such as the death of first-degree relatives in the last 6 months and the loss of a job 3) Any acute and chronic inflammatory disease (including uncontrolled diabetes, rheumatoid arthritis) and infections in the body 4) The presence of malignant disease 5) History of recent surgery and trauma 6) History of allergy to turmeric or other drugs, food and color. 7) taking anticoagulants (heparin, varfarin, enoxaparin) 8) Take vitamin E supplementation, curcumin or estrogen therapy for 3 months prior to study 9) Use of special diets

Age
From **40 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **93**
Actual sample size reached: **84**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants will be assigned randomly blocked blocks with 6 and 9 blocks and 1: 1: 1 assignment to three groups (two intervention groups and one control group) using RAS software.

Blinding (investigator's opinion)
Triple blinded

Blinding description
To hide the allocation, the same black, opaque, and back-numbered glasses (assignment sequences) inside them, either the curcumin capsule or the vitamin E capsule or the placebo capsule, will be used to hide the allocation. Preparation of glasses by an unoccupied person will be done in sampling and collecting data and analyzing them according to the assignment sequence. The first person will be in the condition of glass No. 1 and will continue until the sampling is completed. In all three groups, stratification based on BMI will be done alik

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

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

Street address
Research department., third floor., central construction number 2., Tabriz University of Medical Sciences., Golgasht Street., Azadi Avenue

City
Tabriz

Province
East Azarbaijan

Postal code
5138947977

Approval date
2018-11-19, 1397/08/28

Ethics committee reference number
IR.TBZMED.REC.1397.674

Health conditions studied

1

Description of health condition studied
TAC (Total Antioxidant Capacity)

ICD-10 code
ICD-10 code description

2

Description of health condition studied
(Malondialdehyde) MDA
ICD-10 code
ICD-10 code description

3

Description of health condition studied
hsCRP (high sensitivity C-Reactive Protein)
ICD-10 code
ICD-10 code description

4

Description of health condition studied
Early symptoms of manopause
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
(Total Antioxidant Capacity) TAC
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
TAC levels will be measured with the Biorex kit.

2

Description
(Malondialdehyde) MDA
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Spectrophotometric and Atomic Absorption Comparison (AAS) will be measured.

3

Description
hsCRP (high sensitivity C-Reactive Protein)
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
A turbidometric method based on the formation of a complex resulting from the reaction between hs-CRP and its specific antiserum will be measured.

4

Description
Score of Menopause symptoms and its sub-scales.
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Green Questionnaire

Secondary outcomes

1

Description
Food intake
Timepoint
Before the intervention, one month after the intervention and at the end of the intervention
Method of measurement
24-hour Food record

2

Description
Renal function tests
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using biochemical methods

3

Description
Liver function tests
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using biochemical methods

4

Description
Serum lipid profile
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using biochemical methods

5

Description
Fasting blood sugar
Timepoint
Before intervention and 8 weeks after intervention
Method of measurement
Using biochemical methods

Intervention groups

1

Description
Intervention group: The first Intervention group will receive oral capsules of curcumin twice a day at a dose of 500 milligrams for eight weeks
Category
Treatment - Drugs

2

Description
Intervention group:The second intervention group will receive oral Capsule Vitamin E 200 IU twice a day for eight weeks.
Category
Treatment - Drugs

3

Description
Control group: The control group will receive placebo capsules twice a day for 8 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Health centers selected in Tabriz
Full name of responsible person
Dr. Azizeh Farshbaf Khalili
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Faculty of Nursing and Midwifery., South Shariati St., Tabriz., Iran
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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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Email
iro@tbzmed.ac.ir
Web page address
http://researchvice.tbzmed.ac.ir
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 of Tabriz University of Medical Sciences
Latest degree
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Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
No more information
Study Protocol
No - There is not 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
No - There is not a plan to make this available
Title and more details about the data/document
he results of the clinical study will be published as a paper.
When the data will become available and for how long
Immediately after publishing the results.
To whom data/document is available
All researchers
Under which criteria data/document could be used
Scientific using with citation to article.
From where data/document is obtainable
Farshbafa@tbzmed.ac.ir
What processes are involved for a request to access data/document
Maximum one week after the communication by email.
Comments