

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of oral capsule of curcumin and vitamin E on the hot flush and anxiety in postmenopausal women: a triple blind randomised controlled trial

Protocol summary

Study aim

To determine the effect of oral curcumin and vitamin E capsules on hot flush and anxiety in postmenopausal Women

Design

Randomized controlled clinical trial with three parallel arms.

Settings and conduct

This study will be performed on 93 menopausal women in Ahar city. The researcher will go to the health centers and will provide a list of women around menopausal age along with their phone number, then will call them and they will be invited to participate in the study. In face to face session, eligibility criteria will be assessed and the Green Scale, the Spielberger State-Trait Anxiety Inventory and Female Sexual Function Index will be completed through interview with eligible participants. Participants will be randomly assigned into three groups (two intervention groups and one control group) through block randomization.

Participants/Inclusion and exclusion criteria

Participants will be menopausal women with hot flush at least twice a week.

Intervention groups

The first intervention group will receive oral curcumin capsule, the second intervention group will receive the oral vitamin E capsule and the control group will receive the placebo.

Main outcome variables

The main outcome variables include hot flash and anxiety, which will be assessed by the Green scale and the Spielberger State-Trait Anxiety Inventory, respectively.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N44**

Registration date: **2018-06-23, 1397/04/02**

Registration timing: **prospective**

Last update: **2018-06-23, 1397/04/02**

Update count: **0**

Registration date

2018-06-23, 1397/04/02

Registrant information

Name

Mojgan Mirghafourvand

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

2018-07-04, 1397/04/13

Expected recruitment end date

2018-10-05, 1397/07/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of oral capsule of curcumin and vitamin E on the hot flush and anxiety in postmenopausal women: a triple blind randomised controlled trial

Public title

The effect of curcumin and vitamin E on hot flush and anxiety in postmenopausal women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to participate in the study Having sufficient literacy to complete the questionnaire or the presence of a literate person in the family Normal menopause Being married Women who have been under 6 years old since their menopause. Having at least 40 years and a maximum of 60 Having hot flush at least twice a week

Exclusion criteria:

Use of tobacco and alcoholic beverages and herbal medicines Stressful factors such as the death of relatives in the first six months of the past and loss of occupation Known psychiatric or systemic problems including cardiovascular, digestive, liver, endocrine, etc. Use of any effective medicines for hot flashes (Clonidine, Methyl dopa, Gabapentin, Selective Serotonin Reuptake Inhibitors (SSRIs), Norepinephrine inhibitors (SNRI), and Soy isoflavone Factors that cause vasomotor disorder, such as thyroid disease, according to the person expression Use of any effective medication to treat a person's sexual response (Antihypertensive, Thiazide diuretics, Antidepressant drugs such as Serotonin and Noradrenaline and Reuptake, Antihistamines, Barbiturates, Narcotics, Diazepam, Amphetamines, Cocaine History of allergy to turmeric or other drugs, food and color Taking anticoagulant drugs (Heparin, Warfarin, Enoxaparin)

Age

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

Gender

Female

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **93**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned by block randomization method with a 1: 1: 1 assignment ratio to three groups (two intervention groups and one control group).

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participants, researcher and analyst will be completely blind in this study. The drug and the placebo will be the

same in appearance (shape, color and odor), and the packaging of drugs will be done by someone who is not involved in the research

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

2018-05-27, 1397/03/06

Ethics committee reference number

IR.TBZMED.REC.1397.208

Health conditions studied

1

Description of health condition studied

hot flush

ICD-10 code

N95.1

ICD-10 code description

Menopausal and female climacteric states

2

Description of health condition studied

anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes

1

Description

hot flush

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

Hot flush checklist

2

Description

Anxiety

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

State- Trait Anxiety Inventory

Secondary outcomes

1

Description

Sexual function

Timepoint

Before the intervention, 4 and 8 weeks after the intervention

Method of measurement

FSFI= Female Sexual Function Inventory

Intervention groups

1

Description

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

The second intervention group will receive oral Capsule Vitamin E 200 IU twice a day for eight weeks.

Category

Treatment - Drugs

3

Description

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 in Ahar city

Full name of responsible person

Khatereh Ataei

Street address

Ahar city, East Azarbaijan county, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

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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

Khatereh Ataei

Position

MSc Student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

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Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirgharvand

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Associate Professor

Latest degree

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Other areas of specialty/work

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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

The 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

mirghafourvandm@tbzmed.ac.ir

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

Maximum one week after the communication by email.

Comments

Person responsible for updating data

Contact