Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of oral capsule of curcumin on the fatigue and muscle soreness in postmenopausal women: a randomized controlled trial

Protocol summary

Study aim
To determine the effect of oral curcumin capsules on fatigue and muscle soreness in postmenopausal women

Design
A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 74 postmenopausal women. Blocked randomization method will be used for randomization.

Settings and conduct
The present study is a triple-blind randomized controlled trial (participant, researcher, outcome evaluator and data analyst will be unaware of the treatment received) that will be done in postmenopausal women referred to Sheikh Al-Raees Clinic and Psychiatry Clinic of Imam Reza Hospital in the city of Tabriz.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women with normal menopause; At least one year after amenorrhea; Sufficient literacy to complete the questionnaire or accompany a literate person in the family; Minimum age of 40 years and maximum of 60 years Exclusion criteria: Abuse of tobacco and alcohol; Use of herbal medicines; The occurrence of a stressful event; Psychiatric or systemic disorders; Taking any medication that affects hot flashes and thyroid disease; Taking antidepressants; History of allergy to turmeric or other drugs, allergy to certain foods and food colors; Taking anticoagulants

Intervention groups
Intervention group: Participants (37 women) will receive curcumin tablets with a dose of 500 mg twice a day after meals for 8 weeks. Control group: The Participants (37 women) will receive the placebo tablets with the same order as the intervention group.

Main outcome variables
Fatigue and muscle soreness

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120718010324N72**
Registration date: **2022-10-18, 1401/07/26**
Registration timing: **prospective**

Last update: **2022-10-18, 1401/07/26**
Update count: **0**

Registration date
2022-10-18, 1401/07/26

Registrant information

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Mojgan Mirghafourvand

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
2022-10-21, 1401/07/29

Expected recruitment end date
2023-04-18, 1402/01/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of oral capsule of curcumin on the fatigue and muscle soreness in postmenopausal women: a

randomized controlled trial

Public title
The effect of curcumin on the fatigue and muscle soreness
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Women with normal menopause At least one year after amenorrhea Sufficient literacy to complete the questionnaire or accompany a literate person in the family Age minimum 40 years and maximum 60 years
Exclusion criteria:
Abuse of tobacco and alcohol Use of herbal medicines Occurrence of a stressful event (such as divorce, death of first-degree family members, diagnosis of incurable disease for a family member within the last three months, and loss of job) Psychiatric or systemic disorders (such as cardiovascular, digestive, hepatic, blood, endocrine, and gallstones) Taking any medication that affects hot flashes (clonidine, methyldopa, gabapentin, SSRIs, SNRIs, soy isoflavones), thyroid disease (as reported by women) Taking antidepressants (such as serotonin and noradrenaline reuptake inhibitors, antihistamines, barbiturates, narcotics, diazepam, amphetamines, and cocaine) History of allergy to turmeric or other drugs, allergy to certain foods and food dyes Taking anticoagulants such as heparin, aspirin, clopidogrel, dipyridamole, warfarin, enoxaparin and ticlopidine.
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

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

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants in the study will be assigned to two groups of intervention (recipient of curcumin capsule) and control (recipient of placebo) by block randomization method with block sizes of 4 and 6 and a allocation ratio of 1: 1 and using the website www.random.org . To hide the Allocation (Allocation Concealment), the allocation sequence will be identified by a person not involved in the study using a randomizer, and the curcumin and placebo will be placed in the same packages numbered sequentially.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The participants, researcher and data analyst will be blinded completely in this study. Drug and placebo will be similar in appearance (shape, color, smell) and packaging of drug and placebo will be conducted by a person 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
Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue
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5138947977
Approval date
2022-09-19, 1401/06/28
Ethics committee reference number
IR.TBZMED.REC.1401.560

Health conditions studied

1

Description of health condition studied
Fatigue and muscle soreness
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Fatigue
Timepoint
At the beginning of the study and 8 weeks after the start of consumption
Method of measurement
Short questionnaire of the perimenopausal fatigue scale

2

Description

Muscle soreness

Timepoint

At the beginning of the study and 8 weeks after the start of consumption

Method of measurement

MUSCULOSKELETAL HEALTH QUESTIONNAIRE (MSK-HQ)

Secondary outcomes

1

Description

Depression

Timepoint

At the beginning of the study and 8 weeks after the start of consumption

Method of measurement

Beck Depression Inventory (BDI-13)

Intervention groups

1

Description

Intervention group: The participants (37 people) will receive curcumin oral supplement in the form of tablets with a dose of 500 mg with the trade name (Curcuma ®). The time to take the supplement will be twice a day and after meals. The duration of taking the drug will be 8 weeks from the time of administration.

Category

Treatment - Drugs

2

Description

Control group: The participants (37 people) will receive the placebo in the form of tablets with a dose of 500 mg. The placebo ingredients will consist of corn starch, which will be used at the same time as the curcumin supplement, twice a day and after meals. Also, the duration of taking the placebo will be 8 weeks from the time of administration.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital and Sheikh Al Rais Clinic

Full name of responsible person

Zahra Mousavi

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Sponsors / Funding sources

1

Sponsor

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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

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Full name of responsible person

Sepideh Mashayekh Amiri

Position

Ph.D Student

Latest degree

Master

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Person responsible for updating data

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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