

# 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

##### Name

Mojgan Mirghafourvand

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1479 6969

##### Email address

mirghafourvandm@tbzmed.ac.ir

##### 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](http://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

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

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

##### **Street address**

Azadi Street

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614756

##### **Phone**

+98 41 3334 7059

##### **Fax**

+98 41 3335 2073

##### **Email**

imamreza@tbzmed.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Dr. Parviz Shahabi

##### **Street address**

Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5138947979

##### **Phone**

+98 41 3479 6969

##### **Email**

dabir Khanecent@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**

Sepideh Mashayekh Amiri

##### **Position**

Ph.D Student

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Midwifery

**Street address**

Faculty of Nursing and Midwifery, South Shariati street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

کدپستی: 5138947-977

**Phone**

+98 41 3479 6770

**Email**

Sepidehmashayekh@yahoo.com

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mojgan Mirghafourvand

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Faculty of Nursing and Midwifery, South Shariati street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

کدپستی: 5138947-977

**Phone**

+98 41 3479 6770

**Email**

mirghafourvandm@tbzmed.ac.ir

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Mojgan Mirghafourvand

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Reproductive Health

**Street address**

Faculty of Nursing and Midwifery, South Shariati street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

کدپستی: 5138947-977

**Phone**

+98 41 3479 6770

**Email**

mirghafourvandm@tbzmed.ac.ir

## 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