

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of oral capsule of curcumin on the premenstrual syndrome and dysmenorrhea among students in Tabriz, Iran: a randomized controlled trial

Protocol summary

Study aim

To Determine the effect of oral curcumin capsules on the symptoms of premenstrual syndrome and dysmenorrhea

Design

Clinical trial with control group, parallel groups, triple blinded, randomized, phase 3 on 62 patients, random block method was used for randomization.

Settings and conduct

The present study is a triple-blind randomized clinical trial (participant, researcher, outcome evaluator and data analyst will be blinded to the the type of treatment received) in which the effect of curcumin supplementation on the severity of symptoms of premenstrual syndrome and dysmenorrhea in students of the Tabriz University of Medical Sciences will be investigated.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Regular menstruation (21-35 days); Primary dysmenorrhea and premenstrual syndrome (with VAS score ≥ 4 and PSST score ≥ 20); Age 18-25 years; Not allergic to turmeric; Not taking any medicine to treat the symptoms of premenstrual syndrome at the same time as research
Exclusion Criteria: Abuse of tobacco and alcohol; Use of other herbal medicines; The occurrence of a stressful event; Suffering from any acute or chronic disease; History of any gynecological disease, such as abnormal pelvic anatomy, lack of ovulation, or abnormal pattern of uterine bleeding; Surgery during the last three months; Taking antidepressants and anticoagulants.

Intervention groups

Intervention group: The participants (31 people) will receive curcumin supplement orally with a dose of 500 mg. Control group: The participants (31 people) will receive the placebo with the same order as the intervention group.

Main outcome variables

Premenstrual Syndrome; dysmenorrhea

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N71**

Registration date: **2022-09-18, 1401/06/27**

Registration timing: **prospective**

Last update: **2022-09-18, 1401/06/27**

Update count: **0**

Registration date

2022-09-18, 1401/06/27

Registrant information

Name

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

2022-09-20, 1401/06/29

Expected recruitment end date

2023-03-20, 1401/12/29

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 premenstrual syndrome and dysmenorrhea among students in Tabriz, Iran: a randomized controlled trial

Public title

The effect of curcumin on the premenstrual syndrome and dysmenorrhea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Regular menstruation (21-35 days) Having primary dysmenorrhea and premenstrual syndrome (with VAS score ≥ 4 and PSST score ≥ 20) Age 18-25 years Not allergic to turmeric Not taking any medicine to treat the symptoms of premenstrual syndrome at the same time as the research

Exclusion criteria:

Abuse of tobacco and alcohol Use of other herbal medicines The occurrence of a stressful event (such as the death of a first-degree family member and the diagnosis of an incurable disease for a family member during the last three months) Having any acute or chronic disease (such as epilepsy, cardiovascular, digestive, liver, blood, endocrine) History of any gynecological disease, such as abnormal pelvic anatomy, lack of ovulation, or abnormal pattern of uterine bleeding. Surgery in the last three months Taking antidepressants (such as serotonin and noradrenaline reuptake inhibitors, antihistamines, barbiturates, narcotics, diazepam, amphetamines, and cocaine) Taking anticoagulants such as heparin, aspirin, clopidogrel, dipyridamole, warfarin, enoxaparin and ticlopidine.

Age

From **18 years** old to **25 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The present study is a triple-blind randomized clinical trial. Students will be randomly assigned to curcumin and placebo groups with the block sizes of four and six and allocation ratio of 1:1. To conceal the allocation, same shape, same size, opaque, sealed and consecutively numbered medicine bottles will be used. Inside each medicine bottle, 20 oral capsules of curcumin or placebo will be placed to be taken once a day for a period of 10

days in each menstrual cycle (from 7 days before the start of menstruation to 3 days after the start of menstruation).

Blinding (investigator's opinion)

Triple blinded

Blinding description

The current research is a triple-blind randomized clinical trial in which the participant, clinical caregiver, researcher, outcome assessor, and data analyst were blinded.

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

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East Azarbaijan

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Approval date

2022-08-29, 1401/06/07

Ethics committee reference number

IR.TBZMED.REC.1401.467

Health conditions studied

1

Description of health condition studied

Premenstrual syndrome

ICD-10 code

N94.3

ICD-10 code description

Premenstrual tension syndrome

2

Description of health condition studied

Dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

Premenstrual syndrome

Timepoint

The first assessment before entering the study and the second assessment in one month after the intervention and the third assessment in 2 months after the intervention

Method of measurement

Premenstrual symptoms screening tool (PSST)

2

Description

Dysmenorrhea

Timepoint

The first assessment before entering the study and the second assessment in one month after the intervention and the third assessment in 2 months after the intervention

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The participants (31 people) will receive curcumin oral supplement in the form of gelatin capsules with a dosage of 500 mg with the trade name (Curcuma longa extract complexed with phosphatidyl choline; NOW®). Curcumin supplement contains a combination of curcumin and phosphatidylcholine. The time to take the supplement is once a day and after a meal. The duration of taking the supplement will be 10 days in each menstrual cycle (from 7 days before the start of menstruation to 3 days after the start of menstruation) for two menstrual cycles.

Category

Treatment - Drugs

2

Description

Control group: The participants (31 people) will receive the placebo in the form of capsules 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 once a day and after a meal. Also, the duration of taking placebo will be 10 days in each menstrual cycle (from 7 days before the start of menstruation to 3 days after the start of menstruation) for two menstrual cycles.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Nursing and Midwifery, Tabriz

Full name of responsible person

Dr. Mojgan Mirghafourvand

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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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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

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Person responsible for general inquiries

Contact

Name of organization / entity

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Position

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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