Clinical Trial Protocol
Iranian Registry of Clinical Trials

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

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Tabriz

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East Azarbaijan

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5138947977

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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Reaserch department, third floor, central construction number 2, Tabriz university of medical sciences, Golgasht street, Azadi avenue
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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
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Position
Ph.D Student

Latest degree
Master

Other areas of specialty/work
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Reproductive Health

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Person responsible for updating data

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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