Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Supplementation with Curcuminoids on the Menstrual problems, Severity of Premenstrual Syndrome and Dysmenorrhea; A randomized triple-blind clinical trial

Protocol summary

Study aim

Evaluation of the effect of curcumin on menstrual pattern on severity of premenstrual syndrome and severity of dysmenorrhea

Design

This controlled randomized, triple-blind clinical trial will be conducted on 148 female students of Birjand University of Medical Sciences residing in girls' dormitories. The researcher, patients and statistical analyst were not aware of the type of drug used.

Settings and conduct

Location: Cellular and molecular research center, Birjand University of Medical Sciences, Birjand, Iran The researcher, patients, and statistical analysts were not aware of the type of drug used, and both drugs were produced in identical forms with A and B codes. The study will performed on patients with dysmenorrhea and PMS (n = 174). Intervention group (n = 74), received curcuminoid (500 mg / day); and control group (n = 74) received placebo containing 500 mg corn starch, Seven days before the onset of bleeding, up to three days thereafter, for three successefull menstrual cycles.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of dysmenorrhea and PMS, being single, 18-30 years old, BMI between 19-25. Exclusion criteria: having any acute or chronic illness, as well as having any gynecological disease, abnormal pelvic anatomy, ovulation or abnormal patterns of uterine bleeding.

Intervention groups

1)intervention groups received curcuminoid (n = 74) 2) control groups received placebo (n = 74)

Main outcome variables

Menstrual pattern; severity of premenstrual syndrome and dysmenorrhea

General information

Reason for update

Acronym

طرح کورکومین

IRCT registration information

IRCT registration number: **IRCT20191112045424N1**
Registration date: **2020-01-23, 1398/11/03**
Registration timing: **prospective**

Last update: **2020-01-23, 1398/11/03**
Update count: **0**

Registration date

2020-01-23, 1398/11/03

Registrant information

Name

Afsane Bahrami

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3238 1569

Email address

Afsbahrami91@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-25, 1398/11/05

Expected recruitment end date

2020-03-15, 1398/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of Supplementation with Curcuminoids on the Menstrual problems, Severity of Premenstrual Syndrome and Dysmenorrhea; A randomized triple-blind clinical trial

Public title
The effect of curcuminoids on menstrual disorders
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Simultaneous diagnosis of premenstrual syndrome and primary dysmenorrhea Being single BMI between 19 and 25 Ages 18-25 years Informed consent to participate in the project
Exclusion criteria:
Acute or chronic illness during study The occurrence of a traumatic event such as the death of a relative during the studyMarriage Marriage during study
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
- Data and Safety Monitoring Board

Sample size
Target sample size: **148**
More than 1 sample in each individual
Number of samples in each individual: **2**
Serum, urine
Randomization (investigator's opinion)
Randomized
Randomization description
After careful examination of those with dysmenorrhea and PMS, these individuals are identified and assigned a number ranging from 1 to 148. Then, from numbers 1 through 148, 74 are selected using the random number table, and individuals are assigned to drug A. Then the remaining 74 people receive B medicine
Blinding (investigator's opinion)
Triple blinded
Blinding description
This is a randomized triple-blind controlled clinical trial Initially, the pharmaceutical company determined drug and placebo with two types of A and B codes, and the researcher, patients, and statistical analysts did not know whether A or B was a drug or a placebo. Then, patients were randomly assigned to either group A or group B by random selection. Therefore, the researcher, patients and statistical analyst are kept blind until the end of the study
Placebo
Used
Assignment
Single
Other design features
None

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
National Ethics Committee In Biomedical Research
Street address
Birjand, Ghaffari Street
City
Birjand
Province
South Khorasan
Postal code
9717853577
Approval date
2019-07-15, 1398/04/24
Ethics committee reference number
IR.BUMS.REC.1398.160

Health conditions studied

1

Description of health condition studied
Having both premenstrual syndrome and dysmenorrhea
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
People with premenstrual syndrome and dysmenorrhea
Timepoint
Before intervention, 3 months later
Method of measurement
Premenstrual Syndrome severity questionnaire, digital barometer, digital scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: (n=74) reception of curcuminoids

(500 mg/day), for seven days before the start of bleeding until three days after that for three menstrual cycles

Category

Treatment - Drugs

2

Description

Control group: reception of placebo that resembles curcumin capsules in shape, color and size but contains 500 mg of corn starch, for seven days before the start of bleeding until three days after that for three menstrual cycles

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cellular and Molecular Research Center

Full name of responsible person

Afsane Bahrami

Street address

Ghaffari Street, Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3239 5000

Fax

+98 56 3239 5000

Email

Afsbahrami91@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Afsane Bahrami

Street address

Ghaffari Street, Birjand University of Medical Sciences

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3239 5000

Email

Bahramia@bums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Afsane Bahrami

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Birjand University of Medical Sciences, Ghaffari Ave

City

Birjand

Province

South Khorasan

Postal code

9717853577

Phone

+98 56 3239 1569

Email

Afsbahrami91@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Afsane Bahrami

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Genetics

Street address

Birjand University of Medical Sciences, Ghaffari Ave.

City

Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 915 521 9274
Email
Afsbahrami91@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
Afsane Bahrami
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Genetics
Street address
Ghaffari Street, Birjand University of Medical Sciences
City
Birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 56 3238 1569
Email
Afsbahrami91@yahoo.com

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