

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Study of the effect of Curcumin in patients with Primary Dysmenorrhea

Protocol summary

Study aim

Study of the effect of Curcumin in patients with Primary Dysmenorrhea

Design

Randomized, parallel group, not blinded clinical trial design include 80 patients, phase 3.

Settings and conduct

This study is a clinical trial on 80 patients with primary dysmenorrhea. The severity of dysmenorrhea measured by visual analog scale (VAS) and the need of non-steroidal anti-inflammatory drugs (NSAIDs) will be studied at beginning of the study and two months after the intervention. Patients will be randomly divided into two groups of 40 patients (intervention group and control group). Intervention group will receive two tablets of 500mg curcuma daily for two days before menstruation and three days after menstruation for two successive cycles. Data will be analyzed with SPSS version 23.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with primary dysmenorrhea aged 18 to 30 years old, having at least four recent consecutive painful menstrual cycles during the past six months, bleeding of 3 to 7 days. Exclusion criteria: Taking contraceptives within the past two months, using intra-uterine device or drugs containing Curcumin within the past six months, smoking and alcohol consumption, history of renal stones, granulomatous disease, hyperparathyroidism, and any malignancy.

Intervention groups

Intervention group will receive two tablets of 500mg curcuma daily for two days before menstruation and three days after menstruation for two successive cycles. Control group will receive routine treatment which includes non-steroidal anti-inflammatory drugs (NSAIDs)

Main outcome variables

pain, the number of non-steroidal anti-inflammatory drugs (NSAIDs) used

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180404039187N8**

Registration date: **2020-10-07, 1399/07/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-07, 1399/07/16**

Update count: **0**

Registration date

2020-10-07, 1399/07/16

Registrant information

Name

Elnaz Shaseb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1337 2250

Email address

shasebe@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-11, 1399/05/21

Expected recruitment end date

2021-01-10, 1399/10/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Curcumin in patients with Primary

Dysmenorrhea

Public title
Evaluation effect of Curcumin in patients with Primary Dysmenorrhea

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with Primary Dysmenorrhea Aged 18 to 35 years old Having at least four recent consecutive painful menstrual cycles during the past six months Bleeding of 3 to 7 days during the menstruation
Exclusion criteria:
Taking contraceptives within the past two months Using intra-uterine device or drugs containing Curcumin within the past six months Smoking an alcohol consumption Malignancy

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Arrangement of the randomization process: 1) Determining the volume of each block (quadruple blocks) 2) Preparing the list of the blocks and assigning a number to each of them AABB(1) ABAB(2) ABBA(3) BBAA(4) BABA(5) BAAB(6) 3) Choosing random numbers between 1 and 6 4) Defining the treatment assignment list For example: AABB(1)_BBAA(4)_ABAB(2)_BABA(5)

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not 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 & Technology Dept, Central Building No. 2, Third Floor, Tabriz University of Medical Sciences,

Golghast St, Tabriz

City
Tabriz

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East Azarbaijan

Postal code
5166614766

Approval date
2020-01-06, 1398/10/16

Ethics committee reference number
IR.TBZMED.REC.1398.1091

Health conditions studied

1

Description of health condition studied

Primary dysmenorrhea

ICD-10 code

N94.4

ICD-10 code description

Primary dysmenorrhea

Primary outcomes

1

Description

severity of pain during menstruation

Timepoint

before intervention and 1, 2 months after intervention

Method of measurement

visual analogue scale

2

Description

needs of NSAIDs

Timepoint

before intervention and 1, 2 months after intervention

Method of measurement

DN4 Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:curcuma 500 mg twice daily from 2 days before menstruation until third day of mensuration for 2 months

Category

Treatment - Drugs

2

Description

Control group: routine treatment which includes non

steroidal anti inflammatory drugs (NSAIDs)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Elnaz Shaseb

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Alzahra hospital,Southern Artesh Ave.,Baghshomal
Crossroad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Samiei

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Center of Tabriz Medical University, Daneshgah
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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

Elnaz Shaseb

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Latest degree

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Person responsible for updating data

nilousa22@yahoo.com

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Full name of responsible person

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Position

student

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Medical doctor

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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