Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of curcumin on the intensity of dysmenorrhea pain in endometriosis patients

Protocol summary

Study aim
Determining the effect of curcumin on the severity of dysmenorrhea pain in patients with endometriosis

Design
Clinical trial with control and intervention group, triple-blind and randomized and performed on 50 patients.

Settings and conduct
In this study, patients with endometriosis who refer to the gynecology clinic of Ghaem and Imam Reza (AS) hospitals are included in the study based on inclusion and exclusion criteria. Before starting treatment, on the first day of menstruation, the severity of dysmenorrhea pain in patients is measured using the VAS standard. Then, exactly from the same day (the first day of menstruation), the treatment for the patients starts and the patients of the intervention group are treated with curcumin for three months. In the control group, the treatment will be performed for the same period with placebo capsules. The severity of dysmenorrhea pain on the first day of each menstrual cycle during the treatment period and at the end of treatment is also assessed and compared with the pre-study amount.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of endometriosis based on ultrasound; MRI or surgery (based on persistent cyst or typical endometriosis profile); complaint of dysmenorrhea; age 15-45 years old. Exclusion criteria: treatment with GnRH agonist drugs; intention to conceive

Intervention groups
Patients are randomly divided into two groups of intervention and placebo. The intervention group receives two oral capsules of 40 mg of curcumin (Cinacurcumin, Minoo Pharmaceutical Company, Tehran, Iran) for three months and from the same day (the first day of the menstrual cycle) and the control group receives two placebo capsules for three months. Patients are prescribed.

Main outcome variables
Severe dysmenorrhea pain on the first day of menstruation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201121049457N1**
Registration date: **2021-09-14, 1400/06/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-14, 1400/06/23**
Update count: **0**

Registration date
2021-09-14, 1400/06/23

Registrant information

Name
Malihe Amirian

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-11, 1400/06/20

Expected recruitment end date
2022-02-25, 1400/12/06

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of curcumin on the intensity of dysmenorrhea pain in endometriosis patients

Public title
Effect of curcumin on the intensity of dysmenorrhea pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of endometriosis based on ultrasound, MRI or surgery (based on persistent cysts or typical endometriosis profile) Complaints of dysmenorrhea Age 15-45 years old Informed written consent to participate in the study
Exclusion criteria:
Treatment with GnRH agonist drugs Intention to get pregnant
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients are randomly divided into two groups of intervention and placebo. The intervention group receives two oral capsules of 40 mg curcumin (Cinacurcumin, Minoo Pharmaceutical Company, Tehran, Iran) for three months and from the same day (the first day of the menstrual cycle) and the control group receives two
Blinding (investigator's opinion)
Triple blinded
Blinding description
This is a three-blind study in which the patient, the physician evaluating the outcome, and the outcome analyzer will not be aware of patient grouping. Blinding is done with the help of closed envelopes and randomization is done with the help of a random number table and the envelopes are provided to the patients by the secretary of the clinic.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad university of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street
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Province
Razavi Khorasan
Postal code
13944-91388
Approval date
2021-08-15, 1400/05/24
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1400.282

Health conditions studied

1

Description of health condition studied
Endometriosis
ICD-10 code
N80
ICD-10 code description
Endometriosis

Primary outcomes

1

Description
Severe dysmenorrhea pain
Timepoint
Once every seven days
Method of measurement
By 10-point visual analogue scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: daily administration of two 40 mg curcumin capsules in the intervention group for three months.
Category
Treatment - Drugs

2

Description
Control group: two placebo capsules in the control group for three months and Placebo composed of nanomicels
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mashhad educational hospital clinics
Full name of responsible person
Shima Hatami
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Imam Reza Hospital, Imam Reza Hospital Square
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Sponsors / Funding sources

1

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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
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Shima Hatami
Position
resident
Latest degree
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Gynecology and Obstetrics
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Person responsible for updating data

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All data can be shared after patients are made unidentifiable.

When the data will become available and for how long
Data can be accessible 6 months after results are published.

To whom data/document is available
Data can be accessible through an email to the correspounding author.

Under which criteria data/document could be used
Data will be available for researchers in universities and other scientific institutes.

From where data/document is obtainable
After sending a request email to the correspounding author, data will be sent in 1 month.

What processes are involved for a request to access data/document
Carrying out analysis on data is permitted.

Comments