Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation the effectiveness of the Curcumin as add-on to dienogest in patients with endometriosis.

Protocol summary

Study aim

Evaluation the effectiveness of the Curcumin as add-on to dienogest in patients with endometriosis

Design

After collecting the data, in the first stage, basic clinical and demographic variables will be compared in the intervention and control groups. To compare the mentioned variables, independent t-test, chi-square and Fisher's exact test are used according to the type of variable and the assumptions of the mentioned tests. The method of analysis in this study will be analysis by intention to treat. Multiple imputation method will be used to estimate the missing data. In order to analyze the primary and secondary outcomes of the study, the mixed-effects linear regression statistical test will be used. The results will be calculated and reported as adjusted mean difference with 95% confidence. The variables included in the model include all the variables affecting the outcome, which have been proven in the literature review. A significance level of 0.05 will be considered in all tests. Stata statistical software version 16 will be used for data analysis.

Settings and conduct

All women referred to Ali Bin Abi Taleb (AS) Zahedan Hospital diagnosed with endometriosis and candidates for the prescription of Dingest without previous history of taking hormonal agents.

Participants/Inclusion and exclusion criteria

Women aged 18 to 45 with pain related to endometriosis proven by sonography and examination and history and candidates to receive Dynogest and without previous history of taking hormonal agents.

Intervention groups

Curcumin and dienogest

Main outcome variables

1-the pain 2- Endometrioma size 3- Quality of Life 4- sexual function 5- Housing consumption

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221111056469N1**
Registration date: **2022-11-16, 1401/08/25**
Registration timing: **prospective**

Last update: **2022-11-16, 1401/08/25**
Update count: **0**

Registration date

2022-11-16, 1401/08/25

Registrant information

Name

Mahjob Sargazi taghazi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 915 640 0960

Email address

mahjobsargazi.taghazi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effectiveness of the Curcumin as add-on to dienogest in patients with endometriosis.

Public title

Effectiveness of curcumin in endometriosis.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18 to 45 years experiencing pain associated with endometriosis proven by ultrasound and examination and history No previous history of using hormonal agents Candidate to receive dinogest

Exclusion criteria:

Pregnancy or breastfeeding Amenorrhea The need for surgery after the intervention Previous use of hormonal agents (such as GnRH agonists for 6 months, progestins, dienogest or danazol for 3 months or oral contraceptives for 1 month before the intervention) Abnormal findings in women's examination Abnormal cervical cytology smear in the last 3 months Taking narcotic painkillers before surgery on a daily basis for 2 weeks before surgery Additional surgeries performed or malignancy

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

Sample size is 86 people, of which 43 people will be placed in each group. The block random allocation method was designed by an epidemiologist using WWW.Sealedenvelop.com. The number of considered blocks is 6.

Blinding (investigator's opinion)

Double blinded

Blinding description

The list of random allocation of patients will only be at the disposal of the plan's epidemiologist. In order to hide the random allocation process, random 10-digit codes are written on 86 paper labels without a specific order and framework, which is the identification number of the relevant treatment and only the project methodologist will be aware of the relevant code. The labels will be stuck on the medicine packages in the order of the randomization list. Medicine packages will be arranged in the order of the randomization list inside the box. When the doctor declares the eligibility of a patient, the methodologist will provide the patient with the package treatment plan. The person evaluating the intended outcomes is a third person who is unaware of the randomization process and the type of treatment performed. In order to analyze the data, a statistician who is separate from the study process and is unaware of all the processes will be used. The list of random allocation of patients will only be at the disposal of the plan's epidemiologist. In order to hide the random allocation process, random 10-digit codes are written on 86 paper labels without a specific order and framework, which is the identification number of the relevant treatment and only the project methodologist will be aware of the relevant code. The labels will be stuck on the medicine packages in the order of the randomization list. Medicine packages will be arranged in the order of the randomization list inside the box. When the doctor declares the eligibility of a patient, the methodologist will provide the patient with the package treatment plan. The person evaluating the intended outcomes is a third person who is unaware of the randomization process and the type of treatment performed. In order to analyze the data, a statistician who is separate from the study process and is unaware of all the processes will be used.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Sistan and Baluchestan Province, Zahedan, Integrating the campus of the University of Medical Sciences، doctor، Iran

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2022-10-25, 1401/08/03

Ethics committee reference number

IR.ZAUMS.REC.1401.285

Health conditions studied

1

Description of health condition studied

Endometriosis

ICD-10 code

N80

ICD-10 code description
Endometriosis

Primary outcomes

1

Description
Score Of The Quality of life questionnaire
Timepoint
At the beginning of the study (before the start of the intervention) and 2 months later.
Method of measurement
Specific Questionnaire of Quality of Life in Endometriosis Patient(Endometriosis Health Profile-30)

2

Description
Sexual performance score in the questionnaire
Timepoint
At the beginning of the study (before the start of the intervention) and 2 months later.
Method of measurement
Female Sexual Function index

3

Description
Endometrioma lesion Size
Timepoint
At the beginning of the study (before the start of the intervention) and 2 months later.
Method of measurement
Ultrasound and Medical Examination

4

Description
Pain Score in the Questionnaire
Timepoint
At the beginning of the study (before the intervention) and 2 months later
Method of measurement
Pain Visual Analog Scale Questionnaire

Secondary outcomes

1

Description
Pain Score in the Questionnaire
Timepoint
At the beginning of the study (before the intervention) and 2 months later
Method of measurement
Pain Visual Analog Scale Questionnaire

2

Description
Sexual performance score in the questionnaire
Timepoint
At the beginning of the study (before the intervention) and 2 months later
Method of measurement
Female Sexual Function Index

3

Description
Quality of life score in the questionnaire
Timepoint
At the beginning of the study (before the intervention) and 2 months later
Method of measurement
Specific Questionnaire of Quality of life in Endometriosis Patient(Endometriosis Health Profile-30)

4

Description
Endometrioma lesion size
Timepoint
At the beginning of the study (before the intervention) and 2 months later
Method of measurement
Ultrasound and medical examination

Intervention groups

1

Description
Control group: Control group: control group (dienogest and placebo) will receive a dose of 2 mg of dienogest daily along with placebo.
Category
Placebo

2

Description
Intervention group: Intervention group: Patients in the intervention group (Dinogest and curcumin) will receive a dose of 2 mg dinogest daily. According to the panel of the European Food Safety Authority, the acceptable dose of curcumin is 3 mg per kilogram of body weight. be Patients in the intervention and control groups are prescribed the prescribed dose based on the patient's weight and the frequency of daily use. During the treatment, nanomicelle curcumin 80 and 40 mg of Sinacurcumin company is used.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ali Ibn Abi Talib Hospital, Zahedan
Full name of responsible person

Dr.Maryam Razavi
Street address
Persian Gulf Highway-Salamat Blvd-Ali Ibn Abi Talib (AS) Superspeciality Hospital
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743111
Phone
+98 54 3329 5570
Email
public@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Nur Mohammad Bakhshani
Street address
Zahedan - Doctor Hasabi Square - Medical Sciences Campus
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Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
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Email
public@zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Mahjob Sargazi Taghazi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Zebashahr - Nasr Street - 18 Nasr - Middle of Milan
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Person responsible for updating data

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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