Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effectiveness of oral tablet based on the Cuscuta epithymum on the pelvic pain, the quality of life and the size of the ovarian cyst of patients with endometrioma

Protocol summary

Study aim
Investigation of the effect of oral tablets based on effetimon on the amount of pelvic pain, quality of life, and ovarian cyst size of patients with endometrioma

Design
A controlled, parallel-group, triple-blind, randomized, blocked, phase 2 clinical trial on 68 patients.

Settings and conduct
This study is a triple blind clinical trial, which in the first stage of identification of endometrioma patients will be done by examining and performing two-dimensional transvaginal or abdominal ultrasound in a gynecologist's visit. Patients with endometrioma referred who have pelvic pain and endometrioma cysts larger than 2 cm after ultrasound are divided into two experimental and control groups based on a randomized block method, and each will receive medicine for one month. The drug and placebo, which have the same size, color, taste, and smell, are provided to both groups in completely similar containers by the project partner. Also, the researcher evaluating the intended outcomes is unaware of the random allocation process and the type of treatment performed. Look up details

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Women with endometrioma with pelvic pain and ovarian cysts over 2 cm between the ages of 20 and 45. 2. Absence of Müllerian anomaly, fibrosis, adenomyosis, and myoma. 3. Not taking any medicine except painkillers for endometrioma within 6 months before the visit. Exclusion criteria: 1. Absence of pregnancy or breastfeeding, 2. Severe pain is resistant to treatment that makes the patient a candidate for surgery. 3. Not suffering from acute and serious liver or kidney disease.

Intervention groups
The intervention group includes patients with endometriosis who receive the intervention of Ophtimone tablets. The comparison group includes patients with endometriosis who receive placebo pills.

Main outcome variables
The effect of drugs on patients' pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220108053669N4**
Registration date: **2024-01-14, 1402/10/24**
Registration timing: **prospective**

Last update: **2024-01-14, 1402/10/24**
Update count: **0**

Registration date
2024-01-14, 1402/10/24

Registrant information

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Name of organization / entity
Lorestan University

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-01-21, 1402/11/01

Expected recruitment end date
2024-03-20, 1403/01/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of oral tablet based on the Cuscuta epithymum on the pelvic pain, the quality of life and the size of the ovarian cyst of patients with endometrioma

Public title
Investigating the effectiveness of oral tablet based on the Cuscuta epithymum on endometrioma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Endometriosis with pelvic pain and ovarian cyst over 2 cm Absence of Müllerian fibrosis adenomyosis and myoma Not taking medication such as painkillers Consent
Exclusion criteria:
Patient dissatisfaction Occurrence of pregnancy Drug complication
Age
From **20 years** old to **45 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Random method: random block We consider two intervention and control groups as A and B. If we consider blocks of 4 or 4 people (to reduce the possibility of error), we will have 6 situations as follows: 1.AABB, 2.ABAB, 3.ABBA, 4.BBAA, 5.BABA, 6.BAAB In any case, we assign a number from 1 to 6. Then, by throwing the dice, one state will be determined each time, and based on the order of that state, we will determine the drug or placebo.for example, if the number two comes in the first throw, that means ABAB mode. So first we put medicine number 1 on a can. Then a can containing placebo number 2, drug number 3 and placebo number 4. In the same way, we throw the dice 17 times (for a sample size of 68 people) and number the cans containing medicine and placebo. be unaware
Blinding (investigator's opinion)
Triple blinded
Blinding description
The drug and placebo, which have the same size, color, taste, and smell, are provided to both groups in completely identical containers based on random allocation by the design partner, so none of the patients are aware of the assigned treatment and will not be informed until the end of the study. Also, the researcher evaluating the intended outcomes is unaware of the random allocation 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 and registration committee in clinical trial center of Iran
Street address
Sari, Jouibar interaction, Valiasr boulvard
City
Sari
Province
Mazandaran
Postal code
۳۳۹۷۱-۴۸۱۵۷
Approval date
2023-02-05, 1401/11/16
Ethics committee reference number
IR.MAZUMS.REC.1401.499

Health conditions studied

1

Description of health condition studied
Endometrioma
ICD-10 code
C54.1
ICD-10 code description
Malignant neoplasm of endometrium

Primary outcomes

1

Description
The effect of drugs on patients pain
Timepoint
Monthly since intervention, two months
Method of measurement

VAS(Visual Analogue Scale)

Secondary outcomes

1

Description
Drug effect on ovarian cyst size of patient
Timepoint
Two month since the beginning of intervention
Method of measurement
sonography

2

Description
Drug effect on the quality of life of patients
Timepoint
Monthly since intervention, two month
Method of measurement
EHP-30 Questionnaire

3

Description
Drug effect on the amount of painkillers usage in patients
Timepoint
Monthly since intervention, two month
Method of measurement
asking from patients

Intervention groups

1

Description
Intervention group: The VAS scale is also filled by the patient before the start of the treatment on all days of the period and three times during the day and night. The patient is given 60 tablets of Aftimone (made in the faculty of pharmacy of Mazandaran university of medical science) to be used after breakfast and dinner. Also, patients are allowed to take NSAIDS (with preference to mefenamic acid). After one month, the patients were visited again, the package of medicine and placebo was delivered, and 60 tablets of Aftimone were delivered to the tested group and placebo to the control group for the next month. At this stage, the EHP-30 questionnaire (endometrioma disease quality of life questionnaire) is filled again, and in case of possible side effects, the medication side effects form is also filled. Also, after taking the drug for one month, the patients will fill the VAS scale again on all the days of the period, three times during the day and night. The third visit was two months after the initial visit, the package of medicine and placebo was delivered, and the endometrioma disease quality of life questionnaire will be filled again. The VAS scale will also be filled by the patient at the end of two months of drug use and during the period three times a day. Repeated ultrasound is also performed to determine the size of the ovarian cyst, so that any changes in the size of the patients' endometrioma are investigated.
Category
Treatment - Drugs

2

Description
Control group: The VAS scale is also filled by the patient before the start of the treatment on all days of the period and three times during the day and night. The patient is given 60 tablets of placebo to be used after breakfast and dinner. Also, patients are allowed to take NSAIDS (with a preference for mefenamic acid). After one month, the patients were visited again, the package of medicine and placebo was delivered, and 60 tablets of Aftimone were delivered to the tested group and the placebo to the control group for the next month. At this stage, the EHP-30 questionnaire (endometrioma disease quality of life questionnaire) is filled again, and in case of possible side effects, the medication side effects form is also filled. Also, after taking the drug for one month, the patients will fill the VAS scale again on all the days of the period, three times during the day and night. The third visit was two months after the initial visit, the package of medicine and placebo was delivered, and the endometrioma disease quality of life questionnaire will be filled again. The VAS scale will also be filled by the patient at the end of two months of drug use and during the period three times a day. Repeated ultrasound is also performed to determine the size of the ovarian cyst so that any changes in the size of the patients' endometrioma are investigated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Mazandaran 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
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available