Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the changes in endometrioma size and AMH levels after treatment with Silybum marianum extract in women with endometriosis

Protocol summary

Study aim
Evaluation of the changes in endometrioma size and Anti-Müllerian Hormone levels after treatment with Silybum marianum extract in women with endometriosis

Design
Clinical trial with control group; with parallel groups; double blinded; randomized; design of 60 patients

Settings and conduct
Patient will be assigned into 2 groups with block randomization method, 30 patients will be treated by Silybum marianum and 30 patients will be received bitter pelacebo. Drugs are named to A and B and have been administered in the similar bottle.All patients are visited every 3 months to assess compliance with treatment. The blood level of AMH is evaluated at the beginning of the study and 6 months after the treatment in Amjadi laboratory complex. At the beginning of the study, 6 months later, to evaluate the presence and size of endometrioma, transvaginal or transrectal ultrasound is performed by an expert gynecologist and university faculty member.

Participants/Inclusion and exclusion criteria
Endometriosis recorded by transvaginal ultrasound or transrectal ultrasound by a gynecologist; no history of endometriosis surgery; without any chronic inflammatory disease and chronic medical conditions such as cancer, diabetes, cardiovascular disease and rheumatic disease; Age less than 45 years old; the patient is without surgical indication. Exclusion criteria: breast cancer; if the patient has a condition that worsens with estrogen exposure, she should not use sage extract. Uterine fibroids and possible side effects such as severe nausea, vomiting, diarrhea or gastrointestinal symptoms; previous endometriosis surgery; cervical or ovarian cancer.

Intervention groups
60 subjects will be assigned into 2 groups with block randomization method, 30 patients will be treated by Silybum marianum and 30 patients will be received bitter pelacebo

Main outcome variables
Endometrioma size and AMH level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200925048836N4**
Registration date: **2023-02-25, 1401/12/06**
Registration timing: **prospective**

Last update: **2023-02-25, 1401/12/06**
Update count: **0**

Registration date
2023-02-25, 1401/12/06

Registrant information

Name
Elham Askary
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 71 3233 2365
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-11, 1401/12/20

Expected recruitment end date
2023-05-10, 1402/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the changes in endometrioma size and AMH levels after treatment with Silybum marianum extract in women with endometriosis

Public title
Evaluation of the effect of Silybum marianum on endometriosis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Endometriosis recorded by transvaginal ultrasound or transrectal ultrasound by a gynecologist No history of endometriosis surgery Without any chronic inflammatory disease and chronic medical conditions such as cancer, diabetes, cardiovascular disease and rheumatic disease Age less than 45 years old The patient is without surgical indication

Exclusion criteria:
Breast Cancer probability of side effects such as severe nausea, vomiting, diarrhea or gastrointestinal symptoms Previous endometriosis surgery Cervical or ovarian cancer Uterine fibroid

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

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation method in this study will be the permutation block randomization method, such that "A" represents the subject receiving the intervention (Drug), and "B" represents the subject who receives the placebo. This method is based on 15 blocks in 4 permutations, taking into account all possible quadruple permutations (AABB, ABAB, ABBA, BAAB, BBAA and BABA) and assigning zero to nine (according to a random number table) to each of these permutations, Runs. (AABB Code 0, BABA Code 1, AABB Code 2, BBAA Code 3, BAAB Code 4, and ABBA Code 5 to 9) Then, using a random number table, 15 randomly selected (rows or columns) are selected, and the assigned permutation is written to each number. (The order of placing permutations next to each other is left to right respectively) and how all 60 people will be assigned to two groups A and B.

Blinding (investigator's opinion)
Double blinded

Blinding description
Silybum marianum and pelacebo have been administered in the similar bottles, so patients and researchers were unable to detect which one was Ondansetron or bitter orange peel. Our nurse colleague in this study in hospital delivered formulations to the participants of the study according to Block Balanced Randomization Method by software. She was unaware of the content of the bottles. The researcher had no information about formulation used by each patient while visiting them. At the end of the study, the formulations were decoded and the patients assigned to each group were identified.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Building of Shiraz University of Medical Sciences, Zand Ave

City
Shiraz

Province
Fars

Postal code
34786-71946

Approval date
2023-02-05, 1401/11/16

Ethics committee reference number
IR.SUMS.REC.1401.677

Health conditions studied

1

Description of health condition studied
Endometriosis

ICD-10 code
N80.1

ICD-10 code description
Endometriosis of ovary

Primary outcomes

1

Description
AMH level

Timepoint

Six months after starting the medication

Method of measurement

Hormone kits (Diazist)

2

Description

Endometrioma size

Timepoint

At the beginning of the study and 6 months later

Method of measurement

Transvaginal or transrectal ultrasonography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Silibum Marianum 140 mg twice daily and 30 mg medroxyprogesterone for six months.

Category

Treatment - Drugs

2

Description

Control group: Placebo (starch) tablets twice daily and medroxyprogesterone 30 mg for 6 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari clinic

Full name of responsible person

Dr.Elham.Askari

Street address

Office of Obstetrics and Gynecology, Faqihi Hospital, Zand St.

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7134846114

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Elham Askari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
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
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
Title and more details about the data/document
Statistical Results
When the data will become available and for how long
6 month after the project completion
To whom data/document is available
By obtaining a license from the ethics committee and for scientific and research use in coordination with the main researchers
Under which criteria data/document could be used
The data is for use in this design only. If necessary, after obtaining the necessary permits from the ethics committee
From where data/document is obtainable
To researchers responsible for responding to this plan
What processes are involved for a request to access data/document
Written request Coordinated by the ethics committee 2 months
Comments