

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Ultrasonographic study of the effects of herbal medicine package on Endometriosis

Protocol summary

Study aim

Comparison of the effect of herbal medicine package in the treatment of endometriosis patients

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. The rand function of the Excel software was used for randomization.

Settings and conduct

In this study, patients with ovarian endometriomal cysts less than 80 mm in size were referred to a gynecology clinic and referred to a sonography clinic by a gynecologist. After obtaining conscious consent and having the criteria to enter the study, the mentioned patients will be examined as the target community. Patients will be randomly divided into two groups by block method. In addition to routine OCP treatment, the intervention group receives a combination of herbal medicines. Group B: In addition to OCP treatment, patient receives a routine placebo. After the initial sonography of the uterus to determine the size of the endometriomal cyst and the presence or absence of dysmenorrhea, as well as other symptoms related to the disease, the Iranian medicine specialist provides the patients with the drug. Information is recorded. Finally, the data are compared before and after the intervention. It should be noted that ultrasound is performed by a radiology assistant.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 15 to 49 years Having endometriosis and ovarian endometriosis Exclusion criteria Dissatisfaction Having cardiovascular disease Low platelets Pregnancy or lactation Diabetes History of uterine cancer in the individual or his relatives

Intervention groups

Patients with ovarian endometrioma

Main outcome variables

If we can achieve results, we can use the combination of herbal medicines to help patients and reduce the use of

previous drugs and help improve the quality of life of patients with endometriosis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200701047981N1**

Registration date: **2020-07-22, 1399/05/01**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-22, 1399/05/01**

Update count: **0**

Registration date

2020-07-22, 1399/05/01

Registrant information

Name

Mohamad Manoosian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3333 6421

Email address

mohamadmanoosian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-20, 1399/04/30

Expected recruitment end date

2020-07-31, 1399/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Ultrasonographic study of the effects of herbal medicine package on Endometriosis

Public title

Effects of herbal medicine on endometriosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age: 15 to 49 years old Endometrial disease with ovarian endometrioma

Exclusion criteria:

Dis-satisfaction Cardiovascular disease
Thrombocytopenia Pregnancy / breast feeding Patient with uterus malignancy history or having history in the first degree family Diabetes mellitus

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization of individual blocks using rand function Excel software. The size of the blocks is 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

The radiology assistant, who is also the lead researcher and evaluator of the outcome, along with the participants in the study, as well as the clinical caregiver who specializes in Iranian medicine, as well as the analyst, are all blind. The same package is randomly provided to patients without knowing the contents of the package.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Alam al-Huda St., Shahid Shiroodi St.

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2020-06-14, 1399/03/25

Ethics committee reference number

IR.ARAKMU.REC.1399.108

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**

Ovarian endometrial cyst size

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Ultrasonography

Secondary outcomes**1****Description**

Dysmenorrhea

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

2**Description**

Pelvic pain

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

3

Description

Dysparonia

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

4

Description

Dysuria

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

5

Description

Spotting

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

6

Description

Hypermenorrhea

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

7

Description

Chronic fatigue

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

8

Description

Hematuria

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

9

Description

Painful defecation

Timepoint

At the beginning of the study and 3 months after starting the package of herbal medicines

Method of measurement

Asking patient (yes/ no)

Intervention groups

1

Description

Intervention group: in addition to being treated with routine OCP by a gynecologist, two Aslagh capsules of 500 mg are taken on an empty stomach in the morning (half an hour before breakfast) and two tablespoons at the end of the night. They are not taken during menstruation. Abdominal anointment with chamomile oil will also be done. The duration of treatment will be three months. Aslagh product ingredients: aslagh, fennel, yellow carrot seeds. Ingredients of syrup product: fennel root and seeds, chicory root and seeds, celery seed, cucumber seed, badrang cucumber seeds, melon seed, vinegar , Water, red sugar

Category

Treatment - Drugs

2

Description

Control group: In addition to routine OCP treatment prescribed by a gynecologist, which is in the form of a capsule that is similar to the drug (with the coordination of the pharmaceutical company in the same capsules, flour is poured) and to replace the placebo for the drug syrup similar syrup will be used.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Royan Infertility Treatment Center

Full name of responsible person

Nazila Najdi

Street address

Shahid Beheshti St., Haj Agha Saber Mosque Alley (located behind the mosque), located in the subspecialty center for infertility treatment of Jihad Daneshgahi, Markazi Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
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Shahid Shiroodi St. - Alam Al-Huda St.
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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
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Mohammad Manoosian
Position
Assistant
Latest degree
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Person responsible for scientific inquiries

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Email

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