

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of Achillea Cretica herbal treatment with Dinogest on the pain and size of endometriosis lesions in patients referred to Arash Hospital.

Protocol summary

Study aim

Comparison of the effect of herbal medicine treatment with Achillea Cretica and Dinogest on pain and size of endometrial lesions in patients with endometriosis.

Design

The clinical trial has an intervention and control group, with parallel, double-blind, randomized groups based on 4-size two-allele random number blocks, phase 3, on at least 70 patients.

Settings and conduct

The patient is unaware of the type of treatment received. The final results of the study will be reviewed by a physician who is unaware of the type of intervention. For statistical analysis, a statistician who does not know how to assign individuals to groups is used. The random assignment list of patients is only at the disposal of the clinic secretary. When the physician declares a patient eligible, the clinic secretary provides the envelope to the physician and the treatment is performed according to the type mentioned in the envelope.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women aged 18 to 45 years with pain associated with endometriosis. Exclusion criteria include pregnancy or lactation, amenorrhea within 3 months prior to enrollment, need for endometriosis surgery, previous use of hormonal agents, abnormal findings on gynecological examination, risk factors for decreased bone density

Intervention groups

Patients referred to the laparoscopic clinic of Arsh Hospital who are eligible to enter, if admitted with satisfaction. They are divided into two groups using the randomization block method. The first group receives 2 grams of Dinogest tablets daily for 3 months with rice syrup and the second group receives 2 grams of Dinogest tablets daily with placebo syrup for 3 months.

Main outcome variables

Evaluation of dysmenorrhea, dyspareunia, pelvic pain, and change in size and number of endometriosis lesions in patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220408054455N1**

Registration date: **2022-07-27, 1401/05/05**

Registration timing: **registered_while_recruiting**

Last update: **2022-07-27, 1401/05/05**

Update count: **0**

Registration date

2022-07-27, 1401/05/05

Registrant information

Name

Soheila Sadat Moosavifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 912 633 5414

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-06, 1401/04/15

Expected recruitment end date

2023-02-20, 1401/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Achillea Cretica herbal treatment with Dinogest on the pain and size of endometriosis lesions in patients referred to Arash Hospital.

Public title

The effect of Achillea Cretica herbal medicine on pain and size of endometrial lesions in patients.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women 18 to 45 years old with pain associated with endometriosis

Exclusion criteria:

Pregnancy Breastfeeding The need for endometriosis surgery treatment Amenorrhea within 3 months prior to enrollment Previous use of hormonal agents (e.g., gonadotropin agonists less than 6 months ago, progesterone or danazol less than 3 months ago, or oral contraceptives 1 month before screening) Abnormal findings in gynecological examination Risk factors for decreased bone density (e.g., family history of osteoporosis or use of anticonvulsants or corticosteroids)

Age

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

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Our sample size is 80 people, with 40 people in each group. We will use the block randomization method by using: www.sealedenvelope.com. The number of blocks considered is 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

The random assignment list of patients is only available to the clinic secretary. To hide the random allocation process, the treatment sequence card is written in order, then the cards will be placed in sealed envelopes. On each envelope, a random 10-digit code is written without order and frame, which is the relevant patient

identification number, and only the design methodologist will be aware of the relevant code. When the doctor announces that a patient is eligible, the clinic secretary provides the envelope to the physician and the desired treatment is performed according to the type mentioned in the envelope. Patients do not know the type of syrup they receive and one group is given a placebo and the other group is given medicine. The final results of the study will be reviewed by a physician who is unaware of the type of intervention. For statistical analysis, a statistician who does not know how to assign individuals to groups is used.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of school medicine, Tehran University of Medical Science

Street address

Arash Hospital, Baqdarnia St., East Farjam St., Tehranpars

City

Tehran

Province

Tehran

Postal code

1653915981

Approval date

2021-11-10, 1400/08/19

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.914

Health conditions studied**1****Description of health condition studied**

Endometriosis

ICD-10 code

N80

ICD-10 code description

Endometriosis

Primary outcomes**1****Description**

Degree of dysmenorrhea using visual pain ruler

Timepoint

At the beginning of the study and three months after starting treatment

Method of measurement
Using visual pain ruler

2

Description

Degree of dyspareunia using visual pain ruler

Timepoint

At the beginning of the study and three months after starting treatment

Method of measurement

Using pain ruler

3

Description

Degree of pelvic pain using pain ruler

Timepoint

At the beginning of the study and three months after starting treatment

Method of measurement

Using pain ruler

4

Description

Size change of Endometriosis lesions by Sonography or Laparoscopy

Timepoint

At the beginning of the study and three months after starting treatment

Method of measurement

By performing ultrasound or diagnostic laparoscopy

5

Description

Number Change of endometriosis lesions by performing ultrasound

Timepoint

At the beginning of the study and three months after starting treatment

Method of measurement

By performing ultrasound or diagnostic laparoscopy

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Women aged 18 to 45 years with pain associated with endometriosis, who receive Achillea cretica syrup from Noush Daroo Toosan Salamat Company in addition to one dinogest tablet 2 grams per day for three months.

Category

Treatment - Drugs

2

Description

Control group: Women aged 18 to 45 years with pain associated with endometriosis, who receive placebo Achillea cretica syrup from Noush Daroo Toosan Salamat Company in addition to one dinogest tablet 2 grams per day for three month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Hospital

Full name of responsible person

Reyhaneh Hosseini

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Arash Hospital, Baqdarnia St., East Farjam St., Tehranpars

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Fotohi

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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

Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Soheila Sadat Moosavifar
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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