Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 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)

Phone

+98 912 633 5414

Email address

soheilamoosavifar@gmail.com

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 Laparascopy

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

Street address

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

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7788 3283

Email

hosp_arash@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Fotohi

Street address

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

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Phone

+98 21 7788 3283

Email

hosp_arash@tums.ac.ir

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
Gynecology and Obstetrics

Street address
Arash hospital_Baqdarnia st_East Farjam st_Tehranpars st

City
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Person responsible for scientific 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
Gynecology and Obstetrics

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Person responsible for updating data

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
Gynecology and Obstetrics

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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