Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Jul 2026

The effects of cabergoline in reducing the size of endometrioma endometriosis

Protocol summary

Study aim

Determine the effect of cabergoline on reducing endometrium in patients with endometriosis

Design

This study is three-blind, so that a researcher, a subject and a statistical analyst are unaware of the allocation of the two groups to the study. Since the administration of the drug is in combination with other drugs, the subject is not aware of the status of allocation to the groups. A researcher measuring clinical and diagnostic measures will not be aware of the status of the individual, and the statistician will be unaware of the allocation of people to study groups. Only the observer will be aware of the allocation of the groups. For random assignment, a random block method is used such that individuals use random numbers in quadrilateral blocks. In each group, 32 patient were enrolled in the study.

Settings and conduct

Patients will be included in the study after having explained the study of written consent and ensuring that the criteria for entering the study are randomized and will be assigned to one of two groups according to the randomized randomization strategy and this process will continue until the sample size is completed. . Three months later, the size of the endometrium and the changes will be reviewed. For both groups, the subjects will be measured with transvaginal ultrasonography before and after the intervention, then the mean sizondometrium will be measured. This study is carried out at Rasoul-e-Akram Hospital. The study is three-blind, so that the researcher, the subject and the statistical analyst are unaware of the allocation of the two groups to the study. Since the administration of the drug is in combination with other drugs, the subject is not aware of the status of allocation to the groups. A researcher measuring clinical and diagnostic measures will not be aware of the status of the individual, and the statistician will be unaware of the allocation of people to study groups. Only the observer will be aware of the allocation of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria include one-sided endometrium, less than 5 cm in size, a lack of ultrasound criteria for malignancy, a lack of a malignancy-based measure, an informed consent to enter the study Exclsoin criteria: Dissatisfaction for inclusion in the study, Hormonal therapy including Contraceptive 3 months, sensitivity to cabergolin, age over 45

Intervention groups

In the intervention group, cabergoline is given 0.5 mg twice a week for 12 weeks and control group is receiving placebo

Main outcome variables

size of endometrioma

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150817023666N9**
Registration date: **2018-01-30, 1396/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-30, 1396/11/10**
Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

Abolfazl Mehdizadeh kashi

Name of organization / entity

Iran University of Medical Science

Country

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2020-11-21, 1399/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects of cabergoline in reducing the size of endometrioma endometriosis

Public title
The effects of cabergoline in reducing the size of endometrioma
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
one-sided endometrioma Size less than 5 cm No ultrasound criteria for malignancy The absence of laboratory criteria for malignancy Have informed consent to enter the study Maximum 45 years
Exclusion criteria:
Hormonal treatment includes Contraceptive 3 months before entering the study Cabergolin sensitivity
Age
To **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
for randomization, we are using block randomization which patient put in Foursquare blocks.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study is three-blind, so that a researcher, a patient, and a statistical analyst are unaware of the allocation of the two groups to the study.Since the administration of the drug is in combination with other drugs, the subject is not aware of the status of allocation to the groups. A researcher measuring clinical and diagnostic measures will not be aware of the status of the individual, and the statistician will be unaware of the allocation of people to study groups. Only the observer will be aware of the allocation of the groups
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
Rasoul-e-Akram Hospital, Mazar-i-Mansouri St., Sattarkhan Street
City
tehran
Province
Tehran
Postal code
1445613131
Approval date
2018-01-20, 1396/10/30
Ethics committee reference number
IR.IUMS.REC 1395.95-02-204-28094

Health conditions studied

1

Description of health condition studied
Endometriosis of ovary
ICD-10 code
N80.1
ICD-10 code description
Endometriosis of ovary

Primary outcomes

1

Description
primary outcome: 25% reduction in endometrium size
Timepoint
Treatment is done for 12 weeks for intervention and control groups
Method of measurement
The results of ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving cabergoline
Category
Treatment - Drugs

2

Description
Control group: Placebo recipient
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-e-Akram Hospital
Full name of responsible person
Abolfazl Mehdizadeh-Kashi
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Sponsors / Funding sources

1

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Name of organization / entity
Iran University of Medical Sciences
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Sayed Kazem Malekoti
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Hemat Highway next to Milad Tower, Iran University of Medical Sciences
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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
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Abolfazl Mehdizadeh-Kashi
Position
Professor
Latest degree
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Other areas of specialty/work
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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
Yes - There is 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
Title and more details about the data/document
Data is provided to anyone without the name and part of it
When the data will become available and for how long
A year after printing results
To whom data/document is available
For researchers working in academic and scientific institutions
Under which criteria data/document could be used
Authorized by the author's permission to download and analyze
From where data/document is obtainable
Referring to Endometriosis Research Center
What processes are involved for a request to access data/document
Referring to the Center and endorsing the chairman and research council of the Endometriosis Research Center
Comments