Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the therapeutic effect of vaginal bromocriptine and dienogest on ultrasound and bleeding and pain due to adenomyosis

Protocol summary

Study aim

Determining the effect of treatment, vaginal bromocriptine and dienogest on the ultrasound image and the amount of bleeding and pain caused by adenomyosis.

Design

This is a clinical trial study with two control groups, randomized, double-blind, the study population, the number of 60 patients, 30 people in the control group 1 with vaginal bromocriptine and 30 people in the control group 2 with Dienogest are compared. The rand function of Excel software was used for randomization.

Settings and conduct

This is a clinical, randomized, double-blind experimental study, the study population is adenomyosis patients referred to Rasul Akram Hospital in 2019-1400. The number of 60 people (30 people under treatment group with vaginal bromocriptine and 30 people under treatment group with dienogest) will be included in the study. The procedure will be that TVU will be performed for all patients (vaginal ultrasound ultrasound) at first.

Participants/Inclusion and exclusion criteria

Entry conditions: women with adenomyosis aged 35-35, infertility, use of contraceptive methods, confirmation of the disease using TVU vaginal ultrasound diagnostic tests. Conditions for non-entry: pregnancy or starting treatment for adenomyosis at least 3 months before.

Intervention groups

To determine the effect of treatment. Vaginal bromocriptine and oral dienogest on ultrasound appearance and amount of bleeding and pain caused by adenomyosis. Two control groups, group 1, vaginal bromocriptine treatment and group 2, oral dienogest, are compared.

Main outcome variables

Adenomyosis; menstrual pain; amount of menstrual bleeding, vaginal bromocriptine; Dynogest, ultrasound changes

General information

Reason for update

The following items have been entered incorrectly, please correct them. 1- The time of ultrasound before the intervention is six months and nine months later. 2- In the intervention group, Dienogest 2 mg is a daily oral dose. 3- The realized statistics is 68. 4- Adding the secondary outcome "Uterine position" and removing it from the primary outcomes. 5-Adding the criteria ((use of gonadotropin agonist or antagonist, hormonal contraceptive in the last three months)) in the main conditions of not entering the study before randomization. 6-1- History of specific diseases (including epilepsy, gastrointestinal, cardiovascular, renal disorders) according to the person's own statement. 2- Allergy to dienogest and bromocriptine. 3- Existence of important gynecological disease or abdominal and pelvic surgery in the last 6 months.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230407057838N1**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **retrospective**

Last update: **2023-12-31, 1402/10/10**
Update count: **2**

Registration date

2023-08-21, 1402/05/30

Registrant information

Name
Parvaneh Bahorzahi
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-09-23, 1400/07/01
Expected recruitment end date
2023-03-16, 1401/12/25
Actual recruitment start date
2021-10-02, 1400/07/10
Actual recruitment end date
2022-08-23, 1401/06/01
Trial completion date
2023-03-18, 1401/12/27

Scientific title
Comparison of the therapeutic effect of vaginal bromocriptine and dienogest on ultrasound and bleeding and pain due to adenomyosis

Public title
"vaginal bromocriptine" and" dienogest" on the treatment of adenomyosis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
History of 6 months of painful and regular menstruation
Exclusion criteria:
having a history of specific diseases (including epilepsy, gastrointestinal, cardiovascular, renal disorders) according to the person's own statement. allergies to dienogest and bromocriptine Presence of significant gynecological disease or abdominal and pelvic surgery in the last 6 months - Not using gonadotropin agonist or antagonist, hormonal contraceptive in the last three months.
Age
From **35 years** old to **50 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **68**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
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 Medicine Sciences
Street address
Hazrat Rasool Akram Hospital, Corner of Mansouri Street, Niyaish street, Starkhan street,Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Approval date
2021-09-18, 1400/06/27
Ethics committee reference number
IR.IUMS.FMD.REC.1400.361

Health conditions studied

1

Description of health condition studied
Adenomyosis
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
The intensity of pain at the beginning of the study (before the start of the intervention) and 3, 6 and 9 months after the start of taking the drugs vaginal bromocriptine and dinogest.
Method of measurement
"Visual pain measurement tool" questionnaires are used to evaluate pain.

2

Description
Blood loss
Timepoint
The amount of bleeding is checked at the beginning of the study (before the start of the intervention) and 3, 6, and 9 months after starting the use of vaginal bromocriptine and dinogest.
Method of measurement
A "visual chart of blood loss" is used to evaluate changes in menstrual symptoms.

Secondary outcomes

1

Description
State of uterine view
Timepoint
The condition of the uterus is checked at the beginning of the study (before the start of the intervention) and 6, and 9 months after starting the use of vaginal bromocriptine and dinogest.
Method of measurement
Vaginal ultrasound

Intervention groups

1

Description
Intervention group 1: Bromocriptine (Iran Hormone Company) in the amount of 2.5 mg, 2 tablets, daily, vaginally for 6 months.
Category
Treatment - Drugs

2

Description
Intervention group 2: Dienogest (Iran Hormone Company) at the rate of 1 mg, 2 tablets, daily, oral for 6 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasool Akram Hospital
Full name of responsible person
bahorzahi parvaneh
Street address
Hazrat Rasool Akram Hospital, Corner of Mansouri Street, Niyaish street, Starkhan street,Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Samideh Khoei
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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
Parvaneh Bahorzehi
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)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
"There is no further information".

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available