Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of medroxyprogesterone acetate and dydrogesterone effects on treatment of patients with abnormal vaginal bleeding

Protocol summary

Study aim

main aim of this study is comparison of medroxyprogesterone acetate and dydrogesterone effects on treatment of patients with abnormal vaginal bleeding

Design

The sample size in this study is 176 people who will be randomly divided into two groups receiving medroxyprogesterone acetate or dyrogesterone. after investigating the Inclusion/Exclusion Criteria and obtaining informed consent. Block randomization method is designed by fellow epidemiologist using stata version 13 software.

Settings and conduct

This is a double-blind clinical trial, which will be conducted on 176 women with abnormal vaginal bleeding who are referred to the Arash Hospital's Gynecology Clinic. After obtaining written consent, the participants will be randomly divided into two groups. The first group is treated with medroxyprogesterone acetate tablets (5 mg every 12 hours from the 14th day of the menstrual cycle for 10 days) and the second group will be treated with drogesterone tablets (10 mg every 12 hours from the 14th day of the menstrual cycle for 10 days). The treatment cycle will last for three consecutive months. Complications reported by the patient, drug tolerance, returning to normal cycles (as defined) will be evaluated and ultrasound control will be requested at the end of the sixth month.

Participants/Inclusion and exclusion criteria

Patients with abnormal vaginal bleeding, endometrial thickness greater than 5 mm and no contraindications to taking Progesterone enter the study and patients with endocrine disorders and anatomical problems are excluded from study.

Intervention groups

intervention Group 1: oral medroxyprogesterone acetate tablets; Intervention Group 2: drogesterone tablets

Main outcome variables

Vaginal bleeding; Endometrial thickness; "drugs side effects"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140111016161N7**
Registration date: **2018-08-03, 1397/05/12**
Registration timing: **retrospective**

Last update: **2018-08-03, 1397/05/12**
Update count: **0**

Registration date

2018-08-03, 1397/05/12

Registrant information

Name

Reyhaneh Hosseini

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Science

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of medroxyprogesterone acetate and dydrogesterone effects on treatment of patients with abnormal vaginal bleeding

Public title
Medroxyprogesterone acetate and dydrogesterone effect in the treatment of uterine bleeding
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Endometrial thickness greater than 5 mm Simple endometrial hyperplasia
Exclusion criteria:
Endocrine disorders Anatomical problems; History of hormone therapy History of coagulopathy Contraindication for progestin therapy
Age
From **30 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **176**
Randomization (investigator's opinion)
Randomized
Randomization description
Our sample size is 176 people, with 88 people in each group. Block randomization method was designed by epidemiologist using STATA version 13 software. The number of blocks considered is 4.
Blinding (investigator's opinion)
Double blinded
Blinding description
The random allocation list will solely available to the epidemiologist. 176 cards containing sequences of treatments will be written and be placed inside sealed envelopes. A10-digit random code, as the patient’s identification number, will be provided for each packet. When the physician announces the eligibility of a patient, the methodologist will provide the physician with the envelope. None of the patients should be aware of the type and process of treatment. Also, the person evaluating the outcomes is a third person who is unaware of the random allocation process and type of treatment. Data analysis will be carried out by a statistician who is aware of all the processes performed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences , Deputy of Research
Street address
Qods St, Keshavarz Blvd, Tehran, Iran
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Tehran
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Tehran
Postal code
1417653761
Approval date
2016-12-23, 1395/10/03
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1395.1278

Health conditions studied

1

Description of health condition studied
vaginal bleeding
ICD-10 code
N93
ICD-10 code description
Other abnormal uterine and vaginal bleeding

Primary outcomes

1

Description
vaginal bleeding
Timepoint
At the beginning of the study (before the intervention) and 3 and 6 months after starting the intervention.
Method of measurement
Standard check list designed by the research team

2

Description
endometrium thickness
Timepoint
At the beginning of the study (before the intervention) and 3 and 6 months after starting the intervention.
Method of measurement
sonography

3

Description
Side effects of treatments
Timepoint
At the beginning of the study (before the intervention) and 3 and 6 months after starting the intervention.
Method of measurement
Standard check list designed by the research team

Secondary outcomes

empty

Intervention groups

1

Description
First group: treated with oral medroxyprogesterone acetate tablets, 5 mg every 12 hours from 14th day of menstruation for 10 days. Treatment will continue for 3 months.
Category
Treatment - Drugs

2

Description
Second group: treated with oral dydrogesterone tablets, 10 mg every 12 hours from 14th day of menstruation for 10 days. Treatment will continue for 3 months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Arash women's hospital
Full name of responsible person
Dr Reyhaneh Hoseini
Street address
No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr Mohammad Ali Sahraian
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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
Newsha Mohamad Nejad
Position
Resident
Latest degree
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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
Not applicable
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
Not applicable
Data Dictionary
Not applicable