Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

A Comparative Study on the Clinical Effects and Side Effects of Oral Progesterone versus Vaginal Progesterone for the Treatment of Endometrial Hyperplasia in Patients with Abnormal Uterine Bleeding (AUB)

Protocol summary

Study aim
Comparison of the clinical effects and side effects of oral progesterone with vaginal progesterone for treatment of the patients with endometrial hyperplasia associated with abnormal uterine bleeding (AUB)

Design
A randomized clinical trial, with parallel groups and sample size of 60 (30 in each group)

Settings and conduct
Women with endometrial hyperplasia and uterine bleeding attending to Arash Women's Hospital will be included after obtaining written informed consent. A vaginal ultrasound scan will be performed for and based on ultrasound and clinical signs, an endometrial sample will be collected by curettage or pipelle. Then, subjects without atypia would be included and randomly assigned into two groups. One group will receive oral and the other group will receive vaginal progesterone. Endometrial thickness and biopsy will be re-examined after 3 months. Blood pressure, lipid and glucose profiles, liver function tests, CBC, and participants' weight will be assessed before and three months after the intervention begins. Treatment complications including headache, mastalgia, bloating, and ..., as well as the number of pads used, menstrual delay, period length, Irregular bleeding, menstrual cycles, and clot disposal will be monitored.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Aged 25-70 years old Endometrial hyperplasia without atypia associated with AUB Exclusion criteria: Malignancy Genital infection Contraindication for progesterone use History of hormone therapy during the last 6 months

Intervention groups
Group 1: daily use of 100 mg Actogest vaginal tablets (Actogest company) from 10th to 25th day of the menstrual cycle for 3 months Group 2: Routine treatment with daily 10 mg Medroxyprogesterone oral tablets from 10th to 25th day of the menstrual cycle for 3 months

Main outcome variables
Endometrial thickness, Uterine bleeding, Side effects

General information

Reason for update
Due to the Covid-19 pandemic, the sampling was prolonged.

Acronym

IRCT registration information
IRCT registration number: **IRCT20140820018866N8**
Registration date: **2019-11-10, 1398/08/19**
Registration timing: **prospective**

Last update: **2022-12-28, 1401/10/07**
Update count: **1**

Registration date
2019-11-10, 1398/08/19

Registrant information

Name
Afsaneh Tehranian
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-22, 1398/09/01
Expected recruitment end date
2021-03-19, 1399/12/29
Actual recruitment start date
2019-11-24, 1398/09/03
Actual recruitment end date
2022-05-13, 1401/02/23
Trial completion date
2022-09-21, 1401/06/30

Scientific title
A Comparative Study on the Clinical Effects and Side Effects of Oral Progesterone versus Vaginal Progesterone for the Treatment of Endometrial Hyperplasia in Patients with Abnormal Uterine Bleeding (AUB)

Public title
Oral versus vaginal progesterone for treatment of endometrial hypreplasia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Aged between 25 and 70 years old Endometrial hyperplasia without atypia associated with abnormal uterine bleeding
Exclusion criteria:
Malignancy Genital infection Contraindication for progesterone use such as Haptic disorders or tumor, thromboembolism, etc. History of hormone therapy during last 6 months
Age
From **25 years** old to **70 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization method used in this study will be the block randomization method developed by the statistics expert by using the STATA software in a randomization list format. Then, according to the randomization list, the type of intervention for each individual will be written on paper, and the paper will be put in a sealed envelope. Envelopes will be numbered according to the randomization list. The physician will examine the patient's eligibility, and if the patient is eligible, she will tell the hospital research assistant. The research assistant will then provide the sealed envelope to the physician, and the physician will begin the intervention according to the contents of the envelope.
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 Tehran University of Medical Science
Street address
Tehran University of Medical Science, Qods Street, Keshavarz Boulevard, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1417653761
Approval date
2019-08-11, 1398/05/20
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1398.398

Health conditions studied

1

Description of health condition studied
Endometrial hyperplasia
ICD-10 code
N85.0
ICD-10 code description
Endometrial hyperplasia

Primary outcomes

1

Description
Pathological changes in endometrial sample
Timepoint
At baseline (before the interventions began) and three months after interventions began
Method of measurement
Evaluation of endometrial tissue sample by pathologist for evaluation of cellular changes

2

Description
Vaginal bleeding
Timepoint
At baseline (before the interventions began) and three

months after interventions began

Method of measurement

Number of pads used

3

Description

Hemoglobin level

Timepoint

At baseline (before the interventions began) and three months after interventions began

Method of measurement

A complete blood count (CBC)

Secondary outcomes

1

Description

Clinical side effects of the drug

Timepoint

At baseline (before the interventions began) and three months after interventions began

Method of measurement

Recording clinical side effects including headache, bruising, bloating, nausea and vomiting, weight gain, joint and muscle pain, gastric pain, vaginal itching, uterine pain, as well as delayed menstruation, irregular bleeding, and clotting in a questionnaire.

2

Description

Paraclinical side effects of the drug

Timepoint

At baseline (before the interventions began) and three months after interventions began

Method of measurement

Measurement of blood pressure, lipid and glucose profiles, liver function tests and CBC

Intervention groups

1

Description

Intervention group: daily use of 100 mg Actogest vaginal tablets (Atipharmed Pharmaceutical Company) from 10th to 25th day of the menstrual cycle for 3 months

Category

Treatment - Drugs

2

Description

Control group: Routine treatment with daily 10 mg Medroxyprogesterone oral tablets from 10th to 25th day of the menstrual cycle 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 Afsaneh Tehranian

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
Arash women hospital

Full name of responsible person
Dr. Zahra Molla amin

Position
Resident of Obstetrics and gynaecology

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assistant Professor, Department of obstetrics and gynecology

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Position
Assistant Professor, Department of obstetrics and gynecology

Latest degree
Subspecialist

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