

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

Country

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 hyperplasia

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

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Tehran University of Medical Science, Qods Street, Keshavarz Boulevard, Tehran, Iran

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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

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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

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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
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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

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