

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of diagnostic accuracy of endometrial curettage and aspiration biopsy in patients with endometrial hyperplasia treated with progesterone

Protocol summary

Study aim

Comparing the diagnostic accuracy of Pipel with D&C and the histological results of these two methods in patients with endometrial hyperplasia treated with progesterone

Design

A single-blind, phase 3, single-group clinical trial on 84 pregnant women. The sampling method will be available (non-probability) sampling method.

Settings and conduct

84 women referring to Kosar Qazvin Hospital with AUB who will undergo D&C and will be diagnosed with endometrial hyperplasia, all of whom will undergo a transvaginal ultrasound and endometrial thickness measurement, and no focal lesions will be seen in their ultrasound, will be included in the study. All patients will be fully informed about the aims and methods of the study and their voluntary informed consent will be taken to participate in the study. Patients will be treated with medroxyprogesterone tablets 20 mg daily for 15 days to 3 months (with each treatment regimen). After 4 weeks of completion of treatment, endometrial samples will be taken from each patient through 2 methods: Pipel followed by D&C. In this way, after general anesthesia, a sample of the papule will be taken first, and then dilation and curettage will be performed. The samples will only be sent to a specific pathologist in the form of endometrial samples number one and two (for lack of information) and their results will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women of reproductive age 18-47 years with AUB who underwent D&C and diagnosed with endometrial hyperplasia. Exclusion criteria: The patient's unwillingness to participate in the study; Presence of focal endometrial lesion

Intervention groups

20 mg medroxyprogesterone pills are taken daily for 15 days to 3 months. After 4 weeks, the endometrial sample

will be taken through 2 methods.

Main outcome variables

Endometrial hyperplasia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221008056114N1**

Registration date: **2022-11-22, 1401/09/01**

Registration timing: **prospective**

Last update: **2022-11-22, 1401/09/01**

Update count: **0**

Registration date

2022-11-22, 1401/09/01

Registrant information

Name

Bahar Gholamnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6001

Email address

bahar.gholamnia@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-06, 1401/09/15

Expected recruitment end date

2023-05-05, 1402/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of diagnostic accuracy of endometrial curettage and aspiration biopsy in patients with endometrial hyperplasia treated with progesterone

Public title

Comparison of diagnostic accuracy of endometrial curettage and aspiration biopsy in patients with endometrial hyperplasia

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 18 to 47 years Diagnosis of uterine hyperplasia with AUB Absence of focal lesion

Exclusion criteria:

The patient's unwillingness to participate in the study Improper use of medication Presence of focal endometrial lesion Patient willingness to hysterectomy

Age

From **18 years** old to **47 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **84**

More than 1 sample in each individual

Number of samples in each individual: **2**

Patients will be treated with medroxyprogesterone tablets 20 mg daily for 15 days to 3 months. 4 weeks after completion of treatment, endometrial samples will be taken from each patient through 2 methods: Pipel followed by D&C. In this way, after general anesthesia, a sample of the papule will be taken first, and then dilation and curettage will be performed.

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

This study is one-sided blind. The samples are only sent to a specific pathologist, and in order for the pathologist not to know the type of sample, the samples are sent to pathology under the title endometrial sample 1 (for papillitis) and endometrial sample 2 (for dilatation and curettage) and their results are compared. will be

Placebo

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Qazvin University of Medical Sciences

Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd

City

Qazvin

Province

Qazvin

Postal code

3415613911

Approval date

2021-11-16, 1400/08/25

Ethics committee reference number

IR.QUMS.REC.1400.330

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**

Uterine hyperplasia

Timepoint

Before treatment

Method of measurement

Curtage

Secondary outcomes**1****Description**

Endometrial hyperplasia

Timepoint

Three months after treatment

Method of measurement

Sampling of the endometrium and comparison of pathologies

Intervention groups

1

Description

Intervention group: Medroxyprogesterone tablets 20 mg daily for 15 days to 3 months are placed (with any treatment regimen). After 4 weeks of treatment, endometrial samples will be taken from each patient through 2 methods, Pipell followed by D&C.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Bahar Gholamnia

Street address

Kosar Hospital, Taleghani St., Qazvin

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bahar.gholamnia@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Seyed Mehdi Mirhashmi

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Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd

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research.dpt@qums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Bahar Gholamnia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr Masoumeh Dadashaliha

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Bahar Gholamnia

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)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

The collected information is in the form of a questionnaire and is statistically analyzed.

When the data will become available and for how long

The start of the access period is one year after the results are published.

To whom data/document is available

For obstetricians and researchers working in academic institutions

Under which criteria data/document could be used

Evaluate the path and process of study and analyze it

From where data/document is obtainable

For information, refer to Dr. Bahar Gholamnia. The communication channels are as follows: By sending an email to the address: bahar.gholamnia@ymail.com or referring and contacting Kosar Hospital at the address: Qazvin, Taleghani St. Phone: 028-33236374 Postal address: 34156-13176

What processes are involved for a request to access data/document

After sending the e-mail, the requested information will be reviewed by the facilitator and the person responsible for the scientific responsibility of the study. At your discretion, the requested information will be sent within 10 days of receiving the email.

Comments