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
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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
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Kosar Hospital, Taleghani St., Qazvin
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Dr Seyed Mehdi Mirhashmi
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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
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Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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Resident
Latest degree
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Other areas of specialty/work
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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