

# Accuracy of a novel test in the early detection of endometrial cancer in African women presenting with abnormal uterine bleeding

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<b>Registration date</b> 08/11/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 30/01/2026	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Endometrial cancer, a type of cancer that originates in the lining of the uterus, is a significant health concern for women worldwide. However, the impact of this cancer varies among different populations, and African women often face distinct challenges. While endometrial cancer has a lower incidence in African women compared to other ethnic groups, the mortality rates are alarmingly higher. This disparity in outcomes points towards the urgent need for targeted research and improved diagnostic methods for this specific population.

The existing diagnostic approach for endometrial cancer involves using ultrasound to measure the thickness of the uterine lining. If the lining appears abnormally thick, a biopsy is performed to detect cancer cells. However, this method's accuracy might be compromised in African women due to factors such as the prevalence of conditions like fibroids, which can distort ultrasound readings, and the higher incidence of non-endometrioid type cancers.

To address these challenges, researchers have developed an innovative diagnostic tool known as the WID™-qEC test. This test analyzes specific changes in the DNA of cells collected from the cervix, aiming to identify molecular markers associated with endometrial cancer. Unlike the traditional methods, the WID™-qEC test has the potential to offer a more accurate and reliable means of detecting endometrial cancer in African women.

The primary goal of this study is to rigorously evaluate the diagnostic accuracy of the WID™-qEC test in detecting endometrial cancer in African women presenting with abnormal uterine bleeding. By comparing the results of this new test with those of established diagnostic tools such as ultrasound and biopsy, we (the researchers) intend to determine, if the WID™-qEC test can outperform existing methods in terms of sensitivity and specificity. This objective is crucial in establishing the viability of the new test as a valuable tool for early detection and diagnosis of endometrial cancer.

### Who can participate?

Women aged 40 years or older, who are currently experiencing abnormal bleeding from their womb are eligible to participate in this study.

### What does the study involve?

Traditionally, doctors use ultrasound to assess the thickness of the uterine lining in women with abnormal bleeding. If the lining is thicker than normal, a biopsy is performed to check for cancer. However, this approach may not be as reliable for African women due to potential variations in conditions that can affect the accuracy of the results.

In response, researchers have developed a new test called the WID™-qEC test. This test specifically looks for changes in the DNA of cells collected from the cervix, changes that are associated with endometrial cancer. Medical professionals will gently collect cells from the cervix, which is the lower part of the uterus, using a specialized brush. These collected cells will then be sent to a specialized facility for testing using this new method.

Some of the women participating in the study will receive the new test in conjunction with the usual ultrasound and biopsy procedures. Other women will only undergo the standard tests. The researchers are aiming to compare the performance of the new test with the results obtained from the regular tests and determine if this new test is equally effective or even better than the standard ultrasound method in detecting cancer. Additionally, the researchers will investigate whether the new test can provide insights into the stage and type of cancer a person might have.

### What are the possible benefits and risks of participating?

Participating in this study could potentially assist doctors in discovering a more effective way to detect endometrial cancer in African women. If the new test proves successful, it could simplify and enhance the accuracy of cancer diagnosis. However, as is the case with any study, there are some associated risks. Since the new test is still undergoing testing, its level of accuracy isn't fully established yet. Participants might also experience some degree of discomfort or inconvenience during the sample collection process.

### Where is the study run from?

The study is being conducted at the Cape Coast Teaching Hospital (CCTH) in Ghana.

### When is the study starting and how long is it expected to run for?

September 2022 to December 2023

### Who is funding the study?

1. University College London (UK)
2. The Eve Appeal (UK)
3. HE Samira Empowerment and Humanitarian Projects (Ghana)

### Who is the main contact?

Dr Sebastian Ken-Amoah, [s.ken-amoah@uccsms.edu.gh](mailto:s.ken-amoah@uccsms.edu.gh)

## Contact information

### Type(s)

Principal investigator

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Public, Scientific

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

Nil known

## Study information

**Scientific Title**

Diagnostic accuracy of an epigenetic-based test in the early detection of endometrial cancer in African women presenting with abnormal uterine bleeding

**Study objectives**

WID™-qEC test has a high sensitivity and specificity in detecting endometrial cancer in African women presenting with abnormal vaginal bleeding.

**Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 11/10/2022, Cape Coast Teaching Hospital Ethical Review Committee (Cape Coast Teaching Hospital (CCTH), Cape Coast, -, Ghana; +233 332 1340 1014; ccthresearch@gmail.com), ref: CCTHERC/EC/2022/151

## **Study design**

Prospective cross-sectional cohort study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Early detection and diagnosis of endometrial cancer in African women.

## **Interventions**

Methodology

This research employs an observational cohort design to explore an enhanced method for detecting endometrial cancer. It aims to determine whether the addition of cervicovaginal smear sampling to the standard evaluation protocol can improve diagnostic accuracy for suspected endometrial cancer cases.

Intervention Overview:

Cervicovaginal Specimen Collection: Cervicovaginal smear samples will be gathered using a Cervex-Brush® or Evalyn® for participants who cannot tolerate a speculum. These samples will then undergo the WID-qEC test.

WID-qEC Test: The WID®-qEC test utilises quantitative real-time PCR on bisulfite modified DNA to assess DNA methylation (MethyLight) in the GYPC and ZSCAN12 genes, using COL2A1 as a control. GYPC and ZSCAN12 Percentage of fully Methylated Reference (PMR) values will be calculated.

Standard Evaluation Procedures:

Transvaginal Ultrasonography (TVUS): Ultrasound technology is used to measure endometrial thickness. An endometrial thickness (ET) of 5mm or more is considered indicative of possible endometrial cancer, particularly in postmenopausal women.

Endometrial Biopsy (EB): Participants with an ET of 5mm or more undergo an endometrial biopsy. Pathologists evaluate the tissue sample for histopathological examination.

Participant Pool and Consent:

Women aged 40 or older experiencing abnormal vaginal bleeding are eligible to participate. Potentially suitable patients are invited to join the study, and its objectives are comprehensively explained. Declining participation does not affect their medical care. Informed consent is secured from willing participants. Cervical smear samples are collected, stored, and sent for the WID-qEC test. The WID™-qEC test team remains unaware of patient data to ensure impartiality.

## **Intervention Type**

Other

## **Primary outcome(s)**

Diagnostic accuracy of the WID™-qEC test in detecting endometrial cancer in women with abnormal uterine bleeding. The WID™-qEC test assesses DNA methylation changes in specific gene regions by analyzing cervicovaginal smear samples collected from participants. This test identifies hypermethylation patterns associated with endometrial cancer development.

## **Key secondary outcome(s)**

1. Transvaginal Ultrasonography (TVUS) Accuracy measured by assessing the accuracy of endometrial thickness measurement using TVUS after TVUS is conducted as part of the standard evaluation protocol
2. Endometrial Biopsy (EB) Diagnostic Reliability measured by evaluating the reliability of endometrial biopsy in providing accurate diagnostic information after endometrial biopsy is performed, following a positive TVUS result
3. Patient Experience measured by collecting feedback from participants about their comfort and experience during cervicovaginal smear sample collection
4. Comparative Diagnostic Performance measured by comparing the diagnostic accuracy of the WID™-qEC test with the standard evaluation protocol after completion of data analysis and comparison between the two diagnostic approaches

## **Completion date**

31/12/2023

# **Eligibility**

## **Key inclusion criteria**

Women, aged 40 years and above, who present with abnormal vaginal bleeding

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Mixed

## **Lower age limit**

40 years

## **Upper age limit**

90 years

## **Sex**

Female

## **Total final enrolment**

102

## **Key exclusion criteria**

1. Current pregnancy
2. History of hysterectomy
3. History of cervical or vulval cancer
4. Concurrent other malignancy

**Date of first enrolment**

01/06/2023

**Date of final enrolment**

31/12/2023

## Locations

**Countries of recruitment**

Ghana

**Study participating centre**

**Cape Coast Teaching Hospital**

P.O. Box CT. 1363

Cape Coast

Ghana

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## Sponsor information

**Organisation**

Cape Coast Teaching Hospital

## Funder(s)

**Funder type**

University/education

**Funder Name**

University College London

**Alternative Name(s)**

University College London in United Kingdom, Collegium Universitatis Londinensis, UCL

**Funding Body Type**

Government organisation

## Funding Body Subtype

Universities (academic only)

## Location

United Kingdom

## Funder Name

The Eve Appeal

## Funder Name

HE Samira Empowerment and Humanitarian Projects

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study will be available upon request from Sebastian Ken-Amoah. E-mail: s.ken-amoah@uccsms.edu.gh

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		10/12/2024	30/01/2026	Yes	No
<a href="#">Participant information sheet</a>			17/10/2023	No	Yes