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

Submission date
12/10/2023

Recruitment status
No longer recruiting

Registration date
08/11/2023

Overall study status
Completed

Last Edited
04/03/2024

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

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

Contact information

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Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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
Other

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
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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?
Participant information sheet			17/10/2023	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes