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Evaluating the use of DNA methylation as a tool for cervical cancer screening in sub-Saharan Africa

Submission date
30/10/2025

Recruitment status
No longer recruiting

Registration date
01/11/2025

Overall study status
Completed

Last Edited
31/10/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Cervical cancer is one of the most common and preventable cancers among women worldwide, yet it remains a leading cause of cancer death in sub-Saharan Africa. Effective screening can detect precancerous changes before they progress to cancer, but current screening methods, including cytology and HPV testing, have limitations in low-resource settings due to infrastructure, workforce, and access challenges.

The WID-qCIN test is a new DNA methylation-based test designed to detect changes in cervical cells that indicate the presence of precancer (CIN2/3) or cancer. It can be performed on the same sample used for HPV testing, including self-collected swabs. This study aims to evaluate the diagnostic performance of the WID-qCIN test for identifying cervical precancer and cancer in women in Nigeria, and to assess its feasibility as part of a screening programme in low- and middle-income countries.

Who can participate?
Women aged 25–65 years attending cervical cancer screening or colposcopy clinics at one of three participating hospitals in Nigeria. Participants must be able to give informed consent. Women are excluded if they are pregnant, have had a hysterectomy, a history of cervical or endometrial cancer, previous pelvic radiotherapy, or have received treatment for cervical intraepithelial neoplasia (CIN) in the last six months.

What does the study involve?
This is a multicentre prospective diagnostic accuracy study. After providing informed consent, participants complete a short questionnaire on demographic and medical history, followed by a pelvic examination to collect a cervical sample for cytology and research testing. All participants then undergo colposcopy, and a cervical biopsy is obtained for histology, which serves as the reference standard.

The research sample will be tested for high-risk HPV and analysed using the WID-qCIN DNA methylation test. The results will be compared with cytology, colposcopy, and histology findings

to determine the sensitivity, specificity, and overall diagnostic accuracy of WID-qCIN as a triage test for HPV-positive women.

What are the possible benefits and risks of participating?
There is no direct clinical benefit to participants, but their involvement will contribute to improving cervical cancer screening in Nigeria and other low-resource settings. All procedures are routine in cervical screening and carry minimal risk, such as mild discomfort or spotting after examination or biopsy.

Where is the study run from?
The study is coordinated by University College London (UCL), London UK, in collaboration with University College Hospital, Ibadan, Nigeria, Lagos University Teaching Hospital, Nigeria, and Jos University Teaching Hospital, Nigeria.

When is the study starting and how long is it expected to run for?
Recruitment began in 2023 and is expected to conclude in 2025.

Who is funding the study?
Funding is provided by University College London (global engagement funds), Land Tirol (through its funding for the European Translational Oncology Prevention and Screening (EUTOPS) institute) and HCA healthcare UK.

Who is the main contact?
Dr Ojone Illah
University College London
o.illah@ucl.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Martin Widschwendter

Contact details
University College London
Institute for Women's Health
74 Huntley Street
London
United Kingdom
WC1E 6AU
+44 2076792000
m.widschwendter@ucl.ac.uk

Type(s)
Principal investigator

Contact name
Dr Adeola Olaitan

Contact details
University College London
Institute for Women's Health
74 Huntley Street
London
United Kingdom
WC1E 6AU
+44 2076792000
a.olaitan@ucl.ac.uk

Type(s)
Public, Scientific

Contact name
Dr Ojone Illah

ORCID ID
https://orcid.org/0000-0002-7322-2427

Contact details
University College London
Institute for Women's Health
74 Huntley Street
London
United Kingdom
WC1E 6AU
+44 2076792000
o.illah@ucl.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
23789/001

Study information

Scientific Title
Diagnostic performance of a DNA methylation-based test for cervical cancer screening in Nigerian women

Acronym
PECCAN

Study objectives
Assess the diagnostic performance of the WID™-qCIN test as a triage tool for the detection of premalignant and malignant cervical disease in a population of Nigerian women.

Ethics approval required
Ethics approval required

Ethics approval(s)
1. approved 31/05/2022, Nigeria Health Research Ethics Committee (NHREC) (Department of Health Planning, Research and Statistics, Federal Ministry of Health, 11th Floor, Federal Secretariat Complex Phase III, Ahmadu Bello Way, Abuja, -, Nigeria; +234 95238367; chairman@nhrec.net), ref: NHREC/01/01/2007

2. approved 23/02/2022, UCL Research Ethics Committee (Research Ethics Service Office of the Vice-Provost (Research, Innovation & Global Engagement) University College London, London, WC1E 6BT, United Kingdom; +44 (0) 20 7679 2000; ethics@ucl.ac.uk), ref: 23789/001

3. approved 04/07/2022, University of Ibadan/University College Hospital Ibadan (INSTITUTE FOR ADVANCED MEDICAL RESEARCH AND TRAINING (IAMRAT), College of Medicine, University of Ibadan, Ibadan, -, Nigeria; +234 8023268431; uiuchec@gmail.com), ref: UI/EC/22/0243

4. approved 27/04/2022, Jos University Teaching Hospital Research Ethical Committee (Jos University Teaching Hospital, Lamingo, Jos 930241 Plateau State, Jos, -, Nigeria; +234 903 0001194; juthjos@gmail.com), ref: UTH/DCS/REC/127/XXXI/279

5. approved 30/06/2022, Lagos University Teaching Hospital Health Research Ethics Committee (Room 107, 1stFloor, LUTH Administrative Block, Lagos University Teaching Hospital Ishaga Road, Idi-Araba 102215, Lagos, -, Nigeria; +234 15850737; luthethics@yahoo.com), ref: ADM /DCST/HREC/APP/5095

Study design
Multicentre prospective cross-sectional diagnostic accuracy study

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Screening for cervical cancer

Interventions
All participants provided a cervical sample for HPV and WID-qCIN DNA methylation testing, underwent cytology, colposcopy, and biopsy for histological confirmation. No therapeutic intervention was administered as part of the study.

Intervention Type
Other

Primary outcome(s)
Diagnostic accuracy of the WID-qCIN DNA methylation test for the detection of CIN3+, using histologically confirmed CIN3 or invasive cervical cancer as the reference standard. Measured via

cytology analysis and colposcopic assessment conducted at baseline. Diagnostic performance will be assessed using sensitivity and specificity following completion of laboratory analysis for all participant samples.

Key secondary outcome(s))
1. Diagnostic accuracy (sensitivity and specificity) of cytology and colposcopy for the detection of CIN3+, compared with histology as the reference standard. Measured via cytology analysis and colposcopic assessment conducted at baseline. Diagnostic performance will be assessed using sensitivity and specificity following completion of laboratory analysis for all participant samples.
2. Diagnostic accuracy (sensitivity and specificity) of HPV 16/18 and the composite WID-qCIN /HPV 16/18 test for the detection of CIN3+, compared with histology as the reference standard. Measured via HPV genotyping and WID-qCIN DNA methylation testing on participant samples collected at baseline. Diagnostic performance will be assessed using sensitivity and specificity following completion of laboratory analysis for all participant samples.
3. Comparative performance of WID-qCIN vs cytology and colposcopy as triage tools in hrHPV-positive women. Measured as sensitivity and specificity with 95% confidence intervals following completion of laboratory analysis on all participant samples.
4. Distribution of hrHPV subtypes in the study population. Measured via HPV genotype testing on participant samples collected at baseline.

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Women aged 25–65 years
2. Able and willing to provide written informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
65 years

Sex
Female

Total final enrolment
182

Key exclusion criteria
1. Current pregnancy.
2. History of hysterectomy, cervical or endometrial cancer, or pelvic radiotherapy.
3. Treatment for cervical intraepithelial neoplasia (CIN) within the preceeding six months.
4. Participants receiving ablative treatment at the time of colposcopy (precluding histological sampling).

Date of first enrolment
01/02/2023

Date of final enrolment
18/02/2025

Locations

Countries of recruitment
Nigeria

Study participating centre
University College Hospital Ibadan
Queen Elizabeth Road, Ibadan, Oyo State
Ibadan
Nigeria
N/A

Study participating centre
Jos University Teaching Hospital
Lamingo, Jos 930241
Plateau State
Jos
Nigeria
N/A

Study participating centre
Lagos University Teaching Hospital
Ishaga Road, Idi-Araba 102215
Lagos, Nigeria
Lagos
Nigeria
N/A

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

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
Landes Tirols

Alternative Name(s)
Province of the Tyrol, Tiroler Wissenschaftsfonds

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Austria

Funder Name

HCA Healthcare

Alternative Name(s)
HCA Healthcare, Inc., HCA Healthcare Inc, HCA

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date