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Comparing self-taken samples from the vagina and urine with samples taken by a doctor or nurse in women between 25-65 years who test positive for HPV

Submission date
04/12/2024

Recruitment status
No longer recruiting

Registration date
25/02/2025

Overall study status
Completed

Last Edited
04/03/2025

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 screening is now rapidly moving towards a programme which is primarily based on the detection of high-risk human papillomavirus (hrHPV) based on previous research. The use of hrHPV testing has not only been shown to be far more sensitive than cytology, but does not require a sample taken directly from the cervical transformation zone, so that a self-collected cervical vaginal sample can be used to provide an adequate sample for testing.
Self-sampling for hrHPV is a major new innovation and affords women the option of performing a screening test at home. Home testing is now undertaken during pregnancy and in the context of some sexually transmitted infections. A simplified home test provides an opportunity to replace the current clinician-based service and could revolutionize this costly and time-consuming activity as well as improve coverage rates within the population that is eligible for screening.

Who can participate?
Women aged between 25 and 65 years who are eligible for the cervical screening programme

What does the study involve?
Women will be asked to provide a urine sample with the use of a urine collection device and two vaginal self-samples taken using swabs. Participants will be provided with two urine collection devices and two swabs which will be used to collect the cervico-vaginal samples. After the participant has taken the cervico vaginal self samples using the swabs; one swab will be used as a 'wet' swab where the swab will placed into a medium and one 'dry' swab which does not involve the use of a medium. Participants will be asked to provide a second 3 ml urine sample, ideally on the following day at home and returned to the lab via post. These will be stored in the lab for testing and analysis.

What are the possible benefits and risks of participating?
Currently 1 in 5 women invited for cervical screening do not attend their appointment and as a

consequence of this, their risk of developing cervical cancer increases. Offering an alternative method to the current screening method may increase compliance and improve the timeliness of having their screening test performed within the recommended intervals according to the cervical screening programme. It is anticipated that a screening strategy which includes the use of self-sampling will reduce the number of women being diagnosed with cervical cancer by identifying more disease at the pre-cancerous stage.
Clinician-taken cervico vaginal samples are used regularly for screening for a variety of diseases and are safe for research purposes. Self-collected vaginal samples and urine samples for hrHPV testing are safe tests for research. The study will not have any direct impact on clinical management since all participants will have both a clinically taken sample and a self-sample. Abnormalities detected by the standard clinician-taken sample will be used to determine clinical management. There are no risks associated with the use of the study-specific devices for the collection of self-samples.

Where is the study run from?
Royal London Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2021 to January 2025

Who is funding the study?
Cancer Research UK

Who is the main contact?
1. Prof. Ranjit Manchanda (CI), r.manchanda@qmul.ac.uk
2. Krishna Patel (Project Manager), krishna.patel@qmul.ac.uk

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
311023

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 53997

Study information

Scientific Title
Comparison of high-risk positivity of a vaginal self-sample and urine sample with a clinician-taken cervical sample taken at the same screening visit

Acronym
Predictors 5.2

Study objectives
Phase 1: To evaluate the analytical suitability of self collection methods with time before testing in the laboratory in order to define laboratory processes for sample storage and processing.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/11/2022, London Central Research Ethics Committee (3rd Floor, Barlow House, 4 Minsull Street, Manchester, M1 3DZ, United Kingdom; Nil known; londoncentral.rec@hra.nhs.uk), ref: 22/PR/1146

Study design
Prospective non-inferiority study of paired clinician and self samples within a cervical screening cohort

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
HPV screening for cervical cancer

Interventions
The primary objective of Phase 1 is to evaluate the analytical suitability of storage and laboratory processes to test self-samples using wet and dry self-collection methods for vaginal and urine samples in comparison with the clinician-taken sample.

Women will be asked to provide a urine sample with the use of a urine collection device and two vaginal self-samples taken using swabs. Participants will be provided with two urine collection devices and two swabs which will be used to collect the cervico-vaginal samples. After the participant has taken the cervico vaginal self samples using the swabs; one swab will be used as a 'wet' swab where the swab will placed into a medium and one 'dry' swab which does not involve the use of a medium. Participants will be asked to provide a second 3 ml urine sample, ideally on the following day at home and returned to the lab via post. These will be stored in the lab for testing and analysis.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Novosanis Colli Pee device, CE marked dry Copans FLOQ swab

Primary outcome measure
Quality of DNA (binary) measured using the LabChip GX (PerkinElmer) at each timepoint the sample has been assigned. A GQS of >1.5 will be deemed acceptable sample quality.

Secondary outcome measures
1. Quantity of DNA (ng/ml) as measured using the Qubit Fluorometer (ThermoFisher Scientific) at each timepoint the sample has been assigned
2. Minimum HPV Ct value across all channels measured by the BD assay at each timepoint the sample has been assigned
3. HPV Ct value for each channel, if there’s no infection HPV Ct value will be assigned 40, because they were referred based on having an HPV-positive clinician sample. Measured at each timepoint the sample has been assigned.
4. The time to resuspension in days (continuous) will be calculated as resuspension date – sample collection date
5. S5 overall score (range 0-100, unitless) measured using Pyrosequencing - Pyromark Q48 at timepoints immediately, after 1 week and after 2 weeks from collection
6. The number of 3 ml urine samples returned to the lab measured using the BD Viper™ LT system (BD Viper™ LT system offers fully automated molecular testing for the BD Onclarity™ HPV assay) immediately (there are no timepoints for the 3 ml urine samples)

Overall study start date
01/11/2021

Completion date
30/01/2025

Eligibility

Key inclusion criteria
Women aged between 25-65 years attending the colposcopy clinic as a consequence of abnormal screening cytology and or positive HPV result

Participant type(s)
Healthy volunteer, Patient

Age group
Adult

Lower age limit
25 Years

Upper age limit
65 Years

Sex
Female

Target number of participants
216

Total final enrolment
175

Key exclusion criteria
1. Women who are pregnant
2. Women do not have a cervix
3. History of ablative or excisional treatment for CIN within the last 3 years

Date of first enrolment
01/05/2024

Date of final enrolment
21/10/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal London Hospital, Barts Health
Whitechapel
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Queen Mary University of London

Sponsor details
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Sponsor type
University/education

Website
https://www.qmul.ac.uk/

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Upon study completion, results will be analysed and a report will be generated and used to produce scientific papers for publication and oral presentations at scientific meetings. Final results of the study will be communicated to participating women in a report available on the website. Study progress and milestones will be documented and available on the study website.

Intention to publish date
31/01/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be stored in a non publicly available repository. Participants are made aware of how their data is handled within the patient information sheet and informed consent form.

IPD sharing plan summary
Stored in non-publicly available repository