

# 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

<b>Submission date</b> 04/12/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/02/2025	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/03/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 be 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

**Contact name**  
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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 Minsall 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 be 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, 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