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Catch-up screen project: A urine test for cervical screening

Submission date 07/12/2022	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 31/01/2023	**Overall study status** Ongoing	
Last Edited 20/03/2026	**Condition category** Cancer	

Plain English summary of protocol

Background and Study Aims
Human Papillomavirus (HPV) is known to cause almost all cervical cancers, so testing for HPV is the most effective way to identify women at risk of developing cervical cancer. Since 2019, the NHS Cervical Screening Programme (NHS CSP) has offered primary HPV testing to women aged 25-64 years. Women who have an HPV test before they stop screening are at a very low risk of developing cervical cancer. The “Catch-up Screen” project aims to screen at least 10,000 women aged 60-79 from selected GP practices across the Hull and Manchester areas. The women should have exited the NHS Cervical Screening Programme without a primary HPV test. This includes women who had their last screening invitation before the introduction of primary HPV testing in 2019 and women who did not attend their last test after 2019. Unlike traditional screening, which can sometimes be painful or embarrassing, Catch-up Screen involves women providing a urine sample from the privacy of their home. Urine testing has been shown to be as good as traditional smear tests taken by a nurse for the purpose of HPV testing. It is hoped that urine testing will encourage women who were not screened regularly to become engaged. The aim of this 3-year project is to measure response rates, HPV prevalence and histological outcomes to estimate the likely impact on cervical cancer incidence and mortality of a nationwide catch-up screen programme.

Who can participate?
Women aged between 60 and 79 years old who are no longer being invited for cervical screening as part of the NHS programme

What does the study involve?
Women will be sent a pre-invitation letter and information leaflet prior to receiving a urine sampling kit by post, for them to provide a first void urine sample from home. They will also be asked to complete a short feedback form to find out how they found using the urine kit. Samples will be posted back to the laboratory and tested for HPV. HPV-negative women will receive a letter with their test results, explaining that their future risk of cervical cancer is extremely low. They will not need any further tests. HPV-positive women will be offered a hospital outpatient appointment with a gynaecologist. During this appointment, the

gynaecologist will take a close look at the cervix (this is called a colposcopy) and offer the woman a smear test to check for abnormal cells. If any abnormal cells are found, they can be removed.

What are the possible benefits and risks of participating?
The benefit of taking part is receiving an additional cervical screen which would not usually be offered by the NHS. For most women, who will test negative for HPV, the benefit is the reassurance that they are at very low risk of developing cervical cancer in the future. For those who test HPV positive, the benefit is that cervical cancer can be prevented by identifying and treating abnormal cells. The results will also help the NHS to decide whether a catch-up urine test should be offered to all women in their 60s and 70s.
There are no foreseen disadvantages or risks of taking part. Some people may feel anxious while awaiting results, but most results will be normal. Untreated HPV infections can cause abnormal cells that sometimes if left untreated, progress to cervical cancer. It is therefore important that HPV-positive women attend their hospital appointment because failure to do so puts them at increased risk of future cervical cancer.

Where is the study run from?
Participating GP Practices in the UK

When is the study starting and how long is it expected to run for?
April 2023 to December 2027

Who is funding the study?
Yorkshire Cancer Research (UK)

Who is the main contact?
1. Christine Rake (public), christine.rake@lshtm.ac.uk
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Contact information

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Additional identifiers

Integrated Research Application System (IRAS)
320240

Central Portfolio Management System (CPMS)
54834

Protocol serial number
2022-KEP-893

Study information

Scientific Title
Catch-Up Screen Project: A urine test for cervical screening

Acronym
CUSP

Study objectives
To measure response rates, HPV prevalence and histological outcomes among older women offered a catch-up HPV screen via home urine sampling in order to estimate the likely impact on cervical cancer incidence and mortality of nationwide introduction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 16/01/2023, London-Chelsea Research Ethics Committee (Board Room, Royal Marsden Hospital, The Royal Marsden NHS Foundation Trust, Fulham Road, SW3 6JJ, UK; +44 (0)207 104 8029 / (0)20 7104 8064 / (0)207 104 8356; chelsea.rec@hra.nhs.uk), ref: 22/LO/0854

Primary study design
Interventional

Study design
Multicentre interventional clinical study

Study type(s)
Screening

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

Interventions
This is a one-arm study. The “Catch-up Screen” project will offer the identification of cervical pre-cancer using a catch-up HPV test from a urine self-sample taken at home by women aged 60-79 who have ceased the NHS Cervical Screening Programme without a primary HPV test. This includes women who had their last screening invitation before the introduction of primary HPV testing in 2019 and women who did not attend their last test after 2019.

All participants will be provided with an at-home urine sampling kit (a Colli-Pee device) which reliably collects a standardised volume of first void urine (10ml) for the purpose of HPV testing. Willing participants will post their urine samples back to the laboratory, where they will be tested for HPV. Because HPV is known to cause almost all cervical cancers, testing for HPV will identify women at risk of developing cervical cancer. Unlike traditional screening, which can sometimes be painful or embarrassing, Catch-up Screen offers women the opportunity to provide a urine sample from the privacy of their home for the purpose of detecting the presence of HPV. It is hoped that this will encourage women who were not screened regularly to take part. Women testing HPV positive will be referred for further tests and treatment if necessary. HPV-negative women will receive a letter with their test results, explaining that their future risk of cervical cancer is extremely low. They will not need any further tests. HPV-positive women will be offered a hospital outpatient appointment with a gynaecologist and followed up according to NHS guidelines.

The catch-up screen aims to screen at least 10,000 women across the Hull and Manchester areas via GP practices. In the first year, the feasibility phase, 3,000 women will be invited to test the methodology and determine the uptake, and the second stage will be a wider roll-out inviting about 15,000 women to estimate the rates of pre-cancer detection and cancer prevention. Response rates will be compared among women who receive a phone call from their GP surgery versus those who receive a text message after a study invitation.

Uptake rates, HPV prevalence and diagnoses of pre-cancer and cancer (through linkage to national cancer and death registrations) will aim to discover if at-home urine tests are an effective way to reduce cervical cancer in this older age group.

Intervention Type
Other

Primary outcome(s)
1. Response rate measured as the number of urine samples received divided by the number of eligible women invited at the end of the recruitment period
2. Ease of performing urine test (acceptability) as measured on the feedback form at the time of

consent
3. Preference of urine versus cervical test (acceptability) as measured on the feedback form at the time of consent
4. Colposcopy and histological diagnoses measured using patient records following colposcopy and histology as necessary
5. Cumulative cervical cancer incidence and mortality measured using the national registration at 10 years and 20 years

Key secondary outcome(s)
1. High Risk HPV prevalence measured using the proportion of urine samples testing HPV positive using the BD Onclarity assay at the end of the recruitment period
2. Measure the impact on response rates (as defined in primary outcome measure 1 above) of a follow-up phone call versus text message from the GP practice after the initial invitation

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Female or person with a cervix who is registered with GP practice
2. Ceased from the NHS Cervical Screening Programme without an exit primary HPV test
3. Aged 60-79 years at invitation

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
60 Years

Upper age limit
79 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Previous total hysterectomy
2. Unable to provide a urine sample
3. Unable to understand the Patient Information Sheet and consent form
4. Any condition that would compromise participant safety or data integrity

5. Those who have opted out of sharing data for research purposes (this includes Type 1 and Type 2/National opt-out)

Date of first enrolment
01/01/2024

Date of final enrolment
30/06/2027

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
GP practices from Hull and Manchester - not yet finalised
(Only those invited can take part in the trial)
-
England
-

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Yorkshire Cancer Research

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Other publications	Pilot study results	15/12/2025	18/03/2026	Yes	No