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Urine HPV testing in women over 65 years of age

Submission date
29/04/2022

Recruitment status
No longer recruiting

Registration date
16/05/2022

Overall study status
Completed

Last Edited
18/08/2025

Condition category
Cancer

[X] 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 can save lives from cervical cancer, yet only 7 in 10 women in the UK attend screening, the lowest rate in 20 years. Reasons include embarrassment, fear of speculum examination and inconvenience. Poor attendance is highest amongst women at greatest risk of cervical cancer, including smokers from socio-economically deprived backgrounds. Cervical screening is offered to women aged 25-65 years in the UK, stopping at 65 years partly for historical reasons and partly because speculum examination is uncomfortable for elderly women. Yet deaths from cervical cancer are highest amongst women aged over 70 years, particularly those who haven't attended cervical screening previously. For these reasons, several countries across Europe and Australia have now extended their cervical screening programmes to women aged up to 79 years.
Cervical screening is carried out by collecting cells from the cervix (neck of the womb) with a soft brush. These cells are tested for a virus known to cause cancer called human papillomavirus (HPV). If HPV is detected, the cells are examined under the microscope. If they look abnormal, the woman is referred to a colposcopy clinic, where cells that are
found to be 'pre-cancerous' (cells with the potential to become cancer cells) are identified and treated. To increase screening rates, vaginal 'self-sampling' has been tried, where a woman collects cells from her vagina at home and returns the sample by post, but only 1 in 10 women return the sample. There is therefore an urgent need for new ways to reverse declining rates of cervical screening.
Researchers are developing a urine test that can detect HPV. This test has the potential to remove many of the current barriers to screening and could substantially increase the number of women attending. This study will offer a urine HPV test to women or people with a cervix aged 65 years and older who have exited the cervical screening programme and are attending a Manchester University NHS Foundation Trust (MFT) community-based lung cancer screening service for current and ex-smokers. It will find out whether a one-stop-shop that combines cervical and lung screening is feasible; whether urine HPV testing encourages high-risk non-attenders from underserved communities to be screened; and whether the prevalence of HPV in women aged over 65 years justifies a reappraisal of arbitrary, non-evidence-based age cut-offs for cervical screening.

Who can participate?:
People with a cervix aged 65 to 79 years attending community-based lung health checks

What does the study involve?
Participants will be asked some questions about their health and provide a first void urine sample. They will also be asked to complete a short questionnaire to understand views and preferences around cervical screening. Samples will be tested for high-risk HPV. Participants who test positive will be asked to attend Manchester University NHS Trust for a cervical smear test to check for abnormal cells.

What are the possible benefits and risks of participating?
For most participants, there are no immediate benefits to taking part in this study. For those who test HPV positive, identifying and treating abnormal cells through the NHS Cervical Screening Programme can help prevent future cervical cancer. The results will show whether urine HPV testing could be a reasonable alternative to routine cervical screening for women after they have gone through the menopause. The results will also show if combining cervical screening with lung health checks is successful. The researchers do not expect any side effects from taking part, although appointments will take around 10 – 15 minutes longer.

Where is the study run from?
University of Manchester (UK)

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

Who is funding the study?
Manchester Academic Health Science Centre (UK)

Who is the main contact?
1. Suzanne Carter (public), suzanne.carter@manchester.ac.uk
2. Prof. Emma Crosbie (scientific), emma.crosbie@manchester.ac.uk

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
309115

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 309115, CPMS 51689

Study information

Scientific Title
Urine HPV testing for cervical screening in women over 65: Alternative CErvical Screening (ACES) Over 65's

Acronym
ACES Over 65's

Study objectives
High-risk human papillomavirus (HR-HPV) testing is relevant in women over the age of the UK NHS routine cervical screening age cut off.

Ethics approval required

Old ethics approval format

Ethics approval(s)
Approved 09/02/2022, London - Fulham Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8084; fulham.rec@hra.nhs.uk), ref: 22/SW/0007

Study design
Single-centre observational cross-sectional study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
Identification of cervical cancer risk in women over 65 years of age using urine HPV testing

Interventions
This study will establish the feasibility of combining cancer screening services in a community setting, the uptake of urine HPV testing in underserved communities, and whether the prevalence of HR-HPV in women aged 65-79 justifies reviewing the current age cut off for UK NHS cervical screening.

Women attending community based lung cancer screening clinics will be asked to provide medical history data and a voided urine sample. Urine will be collected with a Colli-Pee device, which reliably collects a standardised volume of first void urine. Urine samples may be provided at the time of the lung health check clinic appointment or collected at home. Samples will be tested for high risk HPV. Women who test HR-HPV positive will be offered a routine cervical sample ('smear test') at MFT and treated according to the results of this sample, using NHS Cervical Screening programme algorithms.

Participants will answer a short acceptability questionnaire to gauge their views on urine testing for cervical screening. Those who decline participation will be asked to record their reasons on a short questionnaire. This is entirely optional

Intervention Type
Other

Primary outcome(s)
Prevalence of HR-HPV in females over 65 years of age measured using a urine sample tested for HR-HPV at baseline

Key secondary outcome(s))
1. Acceptability of urine HPV testing to high-risk past-attenders and non-attenders of routine cervical screening assessed via participant questionnaire at baseline
2. Feasibility of a 'one-stop-shop' that combines cervical and lung screening assessed by uptake of participant appointments over the course of the trial
3. Prevalence of HR-HPV according to screening history in women aged 65-79 years assessed by participant questionnaire at baseline

4. Cervical screening outcomes in women who test HR-HPV positive, including compliance with routine cervical screening, colposcopy, and biopsy, assessed at the final point of treatment or within 12 months

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age 65-79 years
2. Written, informed consent to participate
3. Attending MFT Community based lung health check
4. Female or person with a cervix

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Lower age limit
65 years

Upper age limit
79 years

Sex
Female

Key exclusion criteria
1. Previous total hysterectomy (no cervix)
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

Date of first enrolment
23/05/2022

Date of final enrolment
31/10/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester University Hospital NHS Ft (hq)
Oxford Road
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
University of Manchester

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Research organisation

Funder Name
Manchester Academic Health Science Centre

Results and Publications

Individual participant data (IPD) sharing plan
At the end of the project the researchers will deposit a fully anonymised dataset in an open data repository where it will be permanently stored. Researchers at other institutions can access the anonymised data directly from the repository and use it for further research or to check the analysis and results.
The data will be completely anonymised and stored on Figshare (https://figshare.manchester.ac.uk/). Researchers at other institutions can access the anonymised data directly from the repository. The researchers are seeking consent from participants for this.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No