

Exploring cervical screening without a speculum in women aged 50-64

Submission date 20/07/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
Registration date 04/08/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/08/2022	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

HPV is the name of a very common group of viruses. They do not cause any problems in most people, but some types can cause genital warts or cancer.

Women aged over 65 account for almost half of all cervical cancer deaths, most are in women not adequately screened when aged 50-64. Smears can become uncomfortable after the menopause and this can put some women off coming for cervical screening. One of the main causes of discomfort is the speculum (the instrument used to hold the walls of the vagina open). It is now possible to do cervical screening by testing for the virus that causes cervical cancer; human papillomavirus (HPV). An advantage of HPV testing is that samples can be taken without a speculum. Women can even collect a sample themselves (self-testing). Unfortunately, over half of women who take a self-test worry about not taking a good sample. Another option is to do HPV testing on a sample taken by a clinician without a speculum (non-speculum). Women would have the reassurance of having a clinician take the sample but with much less discomfort. This has not been tried before.

This study will assess the test performance and acceptability of non-speculum clinician samples for HPV testing in women aged 50+.

Who can participate?

There are 2 parallel studies; (i) GP primary care - women aged 50 - 64 attending routine cervical screening (to assess if non-speculum clinician samples can correctly identify women without disease) and (ii) colposcopy - women aged 50+ being investigated for possible cervical disease (to assess if non-speculum clinician samples can correctly identify women with disease).

What does the study involve?

A non-speculum clinician sample will be collected followed by a speculum clinician sample (in the GP study the second sample will be the routine smear). HPV test results from non-speculum samples will be compared with results from speculum samples and routine screening tests. Women in the GP study will complete a short questionnaire asking them about their experiences with the test.

What are the possible benefits and risks of participating?

Benefits: No personal benefit by taking part in this study. However, women will be contributing

to research that will help improve cervical screening in the future.

Risk: We do not anticipate any risks associated with taking part in this study. Vaginal samples are routinely collected in the NHS.

Where is the study run from?

King's College London (UK)

When is the study starting and how long is it expected to run for?

April 2017 to January 2019

Who is funding the study?

Cancer Research UK

Who is the main contact?

Jane Rigney, hpvstudy@kcl.ac.uk

Contact information

Type(s)

Scientific

Contact name

Mrs Jane Rigney

Contact details

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

228847

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

IRAS 228847

Study information

Scientific Title

A cross-sectional study to assess the test performance and acceptability of non-speculum HPV testing in older women

Acronym

SHOW

Study objectives

The test performance and acceptability of non-speculum clinician samples for HPV testing in women aged 50+ is as good as routine cervical screening using a speculum.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 03/08/2017, North East - Tyne & Wear South Research Ethics Committee (Jarrow Business Centre Room 001 Rolling Mill Road, Jarrow, NE32 3DT; UK; +44 (0)207 1048084; tyneandwearsouth.rec@hra.nhs.uk), ref: 17/NE/0268

Study design

Multi centre observational cross sectional study

Primary study design

Observational

Study type(s)

Screening

Health condition(s) or problem(s) studied

Human papillomavirus (HPV)

Interventions

Eligible women will be consented to allow the GP or nurse to take a non-speculum sample before their routine sample. Study samples will be collected using a flocked vaginal swab (this is like a long cotton bud). HPV testing will be performed by the Barts Health NHS Trust Cytology laboratory. Only anonymous data will be collected for the study. This will be provided by the laboratory. HPV test results from non-speculum samples will be compared with results from speculum samples and routine screening tests.

Study HPV results will not be reported to women since they will not inform management (women will be managed according to their usual care under the NHS Cervical screening programme). An exception to this is women in the routine screening arm (GP sub-study) who test cytology negative/HPV positive. These women will be referred by their GP for colposcopy.

Eligible women will be identified by the colposcopy administrative team and sent the study information (invitation letter, patient information leaflet and HPV information sheet) with their colposcopy appointment letter. At their colposcopy appointment written informed consent will be taken by the colposcopist or colposcopist nurse. Before the colposcopy examination, the colposcopist/colposcopist nurse will collect a vaginal sample without a speculum, followed by a sample with a speculum. Almost all of these women will be HPV positive, and many will have high-grade cervical disease. This will allow us to assess how good HPV testing on non-speculum clinician samples is at correctly identifying women with high-grade cervical disease.

Intervention Type

Other

Primary outcome(s)

Measured at a single time point:

1. "Sensitivity" as the proportion of non-speculum HPV positives among (i) speculum HPV positives and (ii) women with high-grade disease (CIN2+ on histology and/or moderate dyskaryosis or worse on cytology)
2. "Specificity" as the proportion of non-speculum HPV negatives among women attending routine screening who are not found to have high-grade disease who are speculum HPV negatives and cytology screen-negative women (normal/borderline/mild dyskaryosis on cytology)

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

31/01/2019

Eligibility

Key inclusion criteria

1. Women aged 50 - 64 years attending routine cervical screening in GP primary care
2. Women aged ≥ 50 years attending colposcopy who are likely or known to be HPV positive (e.g. referred with a cytology result of moderate or worse or positive on HPV triage testing)

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Total final enrolment

298

Key exclusion criteria

1. Women unable to provide informed consent
2. Women whose command of English is not sufficient to obtain informed consent.

Date of first enrolment

20/08/2017

Date of final enrolment

31/01/2019

Locations

Countries of recruitment

United Kingdom

England

Study participating centre**XX Place Health Centre**

Alderney Building
Mile End Hospital Site
Bancroft Road
London
United Kingdom
E1 4DG

Study participating centre**Albion Health Centre**

333 Whitechapel Rd
Shadwell
London
United Kingdom
E1 1BU

Study participating centre**Blithehale Medical Centre**

22 Dunbridge St
London
United Kingdom
E2 6JA

Study participating centre**Whipps Cross Hospital**

Whipps Cross Rd
Leytonstone
London
United Kingdom
E11 1NR

Study participating centre**Royal London Hospital**

Whitechapel Rd
Whitechapel

London
United Kingdom
E1 1FR

Study participating centre
Newham Hospital
Glen Rd
London
United Kingdom
E13 8S

Study participating centre
St Stephen's Health Centre
Bow Community Hall
William Pl
Bow
London
United Kingdom
E3 5ED

Study participating centre
Queens Road Medical Centre
48 Queens Rd
Walthamstow
London
United Kingdom
E17 8PX

Study participating centre
Chrip Street Health Centre
100 Chrip St
Poplar
London
United Kingdom
E14 6PG

Study participating centre
Well Street Surgery
28 Shore Rd
Hackney
London

United Kingdom
E9 7TA

Study participating centre
Somerford Grove Practice
Somerford Grove
Hackney Downs
London
United Kingdom
N16 7UA

Study participating centre
Sorsby Health Centre
3 Mandeville St
Lower Clapton
London
United Kingdom
E5 0DH

Study participating centre
Lower Clapton Health Centre
36 Lower Clapton Rd
Clapton
London
United Kingdom
E5 0PQ

Study participating centre
Jubilee Street Practice
368-374 Commercial Rd
London
United Kingdom
E1 0LS

Sponsor information

Organisation
King's College London

ROR

<https://ror.org/0220mzb33>

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

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Protocol file	version 3.0	18/03/2019	15/08/2022	No	No