ISRCTN69709352 https://doi.org/10.1186/ISRCTN69709352

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

Submission date
20/07/2020

Recruitment status
No longer recruiting

Registration date
04/08/2020

Overall study status
Completed

Last Edited
15/08/2022

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
Kings College London
Faculty of Life Sciences & Medicine
London
United Kingdom
SE1 9RT
+44 (0)2078485494
jane.rigney@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
228847

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 rotuine 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 correctl identifying women with high-grade cervical disease.

Intervention Type
Other

Primary outcome measure
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)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
03/04/2017

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)

Participant type(s)
Mixed

Age group
Adult

Sex
Female

Target number of participants
250

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
England

United Kingdom

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
Chrisp Street Health Centre
100 Chrisp 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

Sponsor details
Faculty of Life Sciences & Medicine
London
England
United Kingdom
SE1 9RT
+44 (0)2078485494
reza.razavi@kcl.ac.uk

Sponsor type
University/education

Website
http://www.kcl.ac.uk/index.aspx

ROR
https://ror.org/0220mzb33

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
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2020

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?
Protocol file	version 3.0	18/03/2019	15/08/2022	No	No
HRA research summary			28/06/2023	No	No