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Does cervical screening without a speculum increase screening uptake in women aged 50-64?

Submission date
06/07/2020

Recruitment status
No longer recruiting

Registration date
04/08/2020

Overall study status
Completed

Last Edited
02/09/2025

Condition category
Cancer

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Annually, around 20% of new cervical cancer diagnoses in the UK occur in women aged 65 and over, and around 50% of the deaths. Most of these cases occur in women who are not adequately screened when aged 50-64. Smear tests can become uncomfortable with ageing and after the menopause and this can put some women off coming for cervical screening (previously known as ‘smear tests’). This is a problem because women who are not screened regularly are at higher risk of developing cervical cancer. One of the main causes of discomfort during a smear test is the speculum (the instrument used to hold the walls of the vagina open). There is another (newer) way we can do cervical screening which is by testing for the virus that causes cervical cancer; known as human papillomavirus (HPV) testing. HPV testing has introduced the possibility of new cervical screening approaches that are likely to be more acceptable to older women, as sampling from the cervix is not necessary and therefore samples can be collected without a speculum. In this study the researchers are offering two different options for non-speculum testing. The first option is a ‘speculum-free clinician test' taken by a practice nurse or GP. The second option is ‘self-test’ which the woman can collect herself in the comfort of her own home. Studies have shown that good quality samples are taken by both of these options and we believe that samples taken by either of these options will be as accurate as a standard screening test. The researchers want to find out if offering women the choice of having a cervical screening test without a speculum will increase screening uptake. They also want to find out how acceptable these tests are to women.

Who can participate?
Women aged 50-64 who are eligible for cervical screening who are at least 12 months overdue but have been screened at least once in the past 15 years according to their GP records (i.e. lapsed attenders at least 1 year overdue screening).

What does the study involve?
Women randomised to the intervention arm who choose to have a non-speculum vaginal sample by their GP or nurse will contact their GP practice to book an appointment where they will have the sample taken. Depending on the preferences of the GP practice, women will be able to book

appointments in at least one of the following ways; by calling the practice (an EMIS alert will be set up to prompt the reception staff about the study), online via EMIS Web ‘Patient Access’ and by text messaging. Participants will also be asked to complete a short questionnaire to assess the acceptability of non-speculum sampling (non-speculum clinician sampling and self-testing) and future screening preferences. Women who are randomised to the control arm will receive the usual cervical screening reminder letter.

What are the possible benefits and risks of participating?
The benefit of taking part is that participants will have the opportunity to have cervical screening without a speculum. Women will also be contributing to research that will help improve cervical screening in the future. The researchers 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?
May 2017 to November 2019

Who is funding the study?
Cancer Research UK

Who is the main contact?
Jane Rigney
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
242943

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 38979, IRAS 242943

Study information

Scientific Title
A pilot study to assess the feasibility and acceptability of offering cervical screening without a speculum to increase uptake in lapsed attenders aged 50-64

Acronym
SHOW2

Study objectives
Offering women the choice of having a cervical screening test without a speculum will increase screening uptake and is acceptable to women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/07/2018, London - Stanmore Research Ethics Committee, Ground Floor (NRES /HRA, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2561; stanmore.rec@hra.nhs.uk), REC ref: 18/LO/1175

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Cervical screening

Interventions
This is a pilot study in primary care which will involve 10-12 GP practices within the Barts Health Catchment area. Eligible women are randomised by the GP practice using computer-generated random numbers (provided by the study team) in a ratio of 1:1 to either the intervention or control arm:
1. Intervention arm - a letter offering the choice of:
1.1. Booking an appointment with their GP or nurse for a non-speculum clinician sample or
1.2. Ordering a self-sampling kit
OR
2. Control arm - Usual cervical screening reminder letter

There is another (newer) way we can do cervical screening which is by testing for the virus that causes cervical cancer; known as human papillomavirus (HPV) testing. HPV testing has introduced the possibility of new cervical screening approaches that are likely to be more acceptable to older women, as sampling from the cervix is not necessary and therefore samples can be collected without a speculum.

In this study the researchers are offering two different options for non-speculum testing. The first option is a 'speculum-free clinician test' taken by a practice nurse or GP. The second option is 'self-test' which the woman can collect herself in the comfort of her own home. Studies have shown that good quality samples are taken by both of these options and we believe that samples taken by either of these options will be as accurate as a standard screening test.

The researchers want to find out if offering women the choice of having a cervical screening test without a speculum will increase screening uptake. They also want to find out how acceptable these tests are to women. Duration of follow up was 12 months

Intervention Type
Behavioural

Primary outcome(s)
Cervical screening uptake: the proportion of women screened (according to GP records) at 4 months from randomisation

Key secondary outcome(s))
1. Cervical screening uptake measured using GP records at 12 months (i.e. long-term cervical screening coverage)
2. Acceptability of non-speculum sampling approaches for cervical screening among women aged 50-64 who are lapsed attendees, assessed using a patient questionnaire data at the time they take the sample
3. The proportion of women who undergo clinician-taken sampling without a speculum versus the proportion who request and return a self-sample, measured using data received from the lab (the number who undergo clinician-taken sampling without a speculum and number who return a self-sample) and coordinating centre data (the number who request a kit) at the end of the study (once data is collected and clean).
4. The proportion of eligible women who test HPV positive and a) attend for follow up (cytology or colposcopy) within 6 months of testing HPV positive on a non-speculum sample and b) who are treated for CIN2+, measured using GP record data at end of the study (once data is collected and clean).
5. Acceptability of non-speculum sampling for cervical screening among the clinical staff who took non-speculum samples from eligible women at GP practices participating in this study, assessed using a swab-taker questionnaire at the end of the study (once recruitment is complete)

Completion date
15/11/2019

Eligibility

Key inclusion criteria
Lapsed cervical screening attenders (i.e. at least 12 months overdue but have attended at least once in the past 15 years)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
Female

Total final enrolment
784

Key exclusion criteria
Women unable to provide informed consent

Date of first enrolment
15/08/2018

Date of final enrolment
15/11/2019

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
Blithehale Medical Centre
22 Dunbridge St
London
United Kingdom
E2 6JA

Study participating centre
Albion Health Centre
333 Whitechapel Rd
Shadwell
London
United Kingdom
E1 1BU

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 datasets generated during and/or analysed during the current study are not expected to be made available. The dataset will be held at KIng's College London for 6 years after the study has finished.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		31/12/2021	02/09/2025	Yes	No
HRA research summary			20/09/2023	No	No
Participant information sheet	Participant information sheet version 3.0	11/11/2025	11/11/2025	No	Yes
Protocol file		18/03/2019	05/10/2022	No	No