ISRCTN39154605 https://doi.org/10.1186/ISRCTN39154605

Response to an invitation to Self-sampling for Human papillomavirus (HPV) versus repeat Invitation for cervical screening in persistent non-responders in NEwcastle upon Tyne

Submission date
03/10/2012

Recruitment status
No longer recruiting

Registration date
04/10/2012

Overall study status
Completed

Last Edited
19/08/2015

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
The aim of this research study is to find out whether women who have already been invited more than once to attend for a cervical smear test, and have not been for one, would be more likely to:
1. respond to another invitation to attend for a cervical smear.
2. respond to the chance to collect their own sample at home which will be tested for HPV (human papillomavirus). HPV is a very common virus which, in some women, can cause abnormal smears and even cancer.
We would also like to find out whether women who have an abnormal test result go on to get themself checked by a doctor or nurse.

Who can participate?
Women who take part will need to live in the Newcastle upon Tyne area and have already been sent at least one invitation and a reminder to attend for a smear test. They will then be sent an invitation with a self-collection test kit (3000 women) or a cervical smear reminder letter (3000 women). Which group each woman will be in is decided completely by chance, for example like tossing a coin.

What does the study involve?
Women who are sent a self-collection kit and would like to take part are asked:
1. to complete a consent form
2. to complete a form with their contact information so that they can receive their results.
3. to read the HPV Test Instruction Sheet enclosed and take their sample.
4. to package and send as explained on the instruction sheet. The postage is pre-paid and does not cost the woman herself any money.
The sample is sent to the Centre for Cancer Prevention where it is tested for HPV. Women will receive their test result in a letter. All women are advised that they should still consider attending for a smear test but especially if the HPV result is abnormal (positive). Women with

this result will be asked to go to their GP or a sexual health clinic for a cervical smear. If the HPV test is negative we would still encourage her to attend for a smear test but she can be reassured that your risk of having an abnormality on her cervix is lower. We will also write to the woman's GP letting him or her know that she is taking part in the study and her test result.

What are the possible benefits and risks of participating?
We believe that there are no specific risks from taking the tests; in the studies we have already carried out using this self-test, women told us they did not encounter any particular problems. Some women find making time to have a cervical smear difficult or the test uncomfortable or embarrassing when taken in a clinic. Those who take part in this study will be able to try using a test at home, without the need for an appointment. It is also hoped that we can collect some useful information which will be published in a professional journal. This would mean that what we learn may benefit women in the future.

Where is the study run from?
The study is being run from the Centre for Cancer Prevention at the Wolfson Institute of Preventive Medicine, Queen Mary University of London.

When is the study starting and how long is it expected to run for?
The study will start in September 2012 and women invited will be given three months to return their sample. After this the study teams will be looking at whether women have been for smear tests or further checks following on from this. It should all be finished in just over a year.

Who is funding the study?
Cancer Research UK

Who is the main contact?
Dr Anne Szarewski
Louise Cadman
cervix.studies@qmcr.qmul.ac.uk

Contact information

Type(s)
Scientific

Contact name
Ms Louise Cadman

Contact details
Wolfson Institute of Preventative Medicine
Charterhouse Square
London
United Kingdom
EC1M 6BQ
-
l.cadman@qmul.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
13096

Study information

Scientific Title
A pragmatic randomised controlled trial of response to an invitation to self-sampling for human papillomavirus (HPV) versus repeat invitation for cervical screening in persistent non-responders in Newcastle upon Tyne

Acronym
SHINE

Study objectives
In recent years attendance for cervical screening has been falling with coverage now below the NHS Cervical Screening Programme (NHSCSP) stated target of 80%. Self-sampling means the woman can collect a sample (using a swab, a bit like a long cotton bud) in the comfort and privacy of her own home, without the need for a speculum (which is the instrument used to open the vagina often responsible for the discomfort which may be felt). We have already carried out studies which have shown that women of different educational levels find this self-test easy to do without help, only using a leaflet which we developed with the help of psychologists.

There have been studies in Scandinavian countries and Holland, in which they found that around a third of the non-attenders were willing to send back a self-sample. The only UK study to date of HPV self-sampling in persistent non-responders was carried out in Westminster, London (Szarewski et al, 2011) and showed a low uptake of 6.4%. We are concerned that that study was not representative of the UK, and therefore wish to do a study in a more stable population. Newcastle upon Tyne is a mixed urban / rural location, typical of the UK and results from this socially heterogeneous population are more likely to be representative of the broader UK population.

We will randomly select 6000 non-attenders in the Newcastle upon Tyne region: half will just be sent a further invitation for a smear and the other half will be sent a self-sampling kit, together with information and consent forms to sign. We will then compare how many women send back a self-test or attend for cytology, and also go for further investigations if necessary.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=13096

Ethics approval required
Old ethics approval format

Ethics approval(s)
Sunderland Research Ethics Committee, First MREC approval date 23/07/2012, ref: 12/NE/0242

Study design
Randomised; Interventional; Design type: Screening

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
Not available in web format, please contact cervix.studies@qmcr.qmul.ac.uk to request a patient information sheet

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

Interventions
Self-collection: Women who have failed to attend for cervical cytology screening and have reached Point 4 as detailed above (NEPCSA cervical screening invitation schedule) will be posted an invitation letter to take their own HPV self-sample, a Participant Information Leaflet (PIL) and ICF, an HPV self-sampling test instruction sheet and an HPV self-sampling test kit.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Response to the intervention - The proportion of women responding to the intervention.

Secondary outcome measures
1. The proportion of women responding to the intervention by returning the HPV self-sampling test within 3 months
2. The proportion of women responding to the intervention by attending for cervical cytology within 3 months
3. The proportion of women responding to the further invitation to attend for cervical cytology within 3 months
4. The proportion of women attending for a cervical cytology within 3 months having had a positive HPV test
5. The proportion of women attending for colposcopy (within 7 months of being sent their HPV self-sampling kit) having had a positive HPV test and abnormal cervical cytology of borderline or mild dyskaryosis and HPV triage positive or cytology of moderate dyskaryosis or worse.
6. The proportion of women in the comparator group attending for colposcopy within 3 months of abnormal cervical cytology of borderline or mild dyskaryosis and HPV triage positive or cytology of moderate dyskaryosis or worse
7. The proportion of women in the comparator group attending for colposcopy within 3 months

of abnormal cervical cytology of borderline or mild dyskaryosis and HPV triage positive or cytology of moderate dyskaryosis or worse compared with the proportion of women attending for colposcopy (within 7 months of being sent their HPV self-sampling kit) having had a positive HPV test and abnormal cervical cytology of borderline or mild dyskaryosis and HPV triage positive or cytology of moderate dyskaryosis or worse

Overall study start date
10/09/2012

Completion date
10/12/2013

Eligibility

Key inclusion criteria
Non-responders according to the North East Primary Care Services Agency (NEPCSA) recall process. They will have received their initial screening letter, plus a first reminder letter, plus at least two non-responder cards will have been sent to their General Practitioner, identified using the NEPCSA Exeter National Health Applications and Infrastructure Services (NHAISs) System.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Key exclusion criteria
1. Women who have written to the NEPCSA to document their refusal to take part in the NHSCSP
2. Women who contact the trial team and ask to be excluded from the trial
3. Pregnancy
4. Total abdominal hysterectomy
5. Never been sexually active
6. Women who are identified as becoming pregnant or undergoing hysterectomy following the initial test will be excluded from the analysis of data for secondary outcomes
7. HPV self-sample returned without a signed Informed Consent Form (ICF) (the Participant Information Leaflet (PIL) will state that samples returned without a signed consent form cannot be processed)
8. Informed Consent Form (ICF) returned with incomplete contact details whereby the test results cannot be sent

Date of first enrolment
10/09/2012

Date of final enrolment

10/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wolfson Institute of Preventative Medicine
London
United Kingdom
EC1M 6BQ

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
Joint R&D Office
5 Walden Street
London
England
United Kingdom
E1 2EF

Sponsor type
University/education

ROR
https://ror.org/026zzn846

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK (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
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2015		Yes	No