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Human Papillomavirus (HPV) testing on self-collected samples to increase uptake of cervical screening in non-attenders

Submission date	Recruitment status	[X] Prospectively registered
21/11/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/11/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/07/2017	Infections and Infestations	

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-hpv-self-testing-for-women-who-have-not-been-for-cervical-screening

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15712

Study information

Scientific Title
Human Papillomavirus (HPV) testing on self-collected samples to increase uptake of cervical screening in non-attenders: a pilot study

Study objectives
The aim of this study is to assess the feasibility and acceptability of offering vaginal self-sampling for HPV testing in general practice to cervical screening non-attenders to increase coverage.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South East Coast – Brighton & Sussex Research Ethics Committee, 24/10/2013, ref: 13/LO/1441

Study design
Non-randomised; Interventional; Design type: Screening

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
GP practice

Study type(s)
Screening

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Topic: Primary Care Research Network for England; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Women aged 28-64 who are at least 6 months overdue their smear will be flagged in the EMIS electronic patient record system at GP surgeries. GPs, nurses and healthcare practitioners will be asked to offer flagged women a self-sampling study kit for HPV testing, when they consult for any reason. Women will take their sample in the GP surgery bathrooms or at home. Samples will be analysed by Barts Health NHS Trust pathology lab.

Results will be sent to the women via post. Women who test HPV negative will be exited from the study. Women who test HPV positive will be asked to attend their GP surgery for a smear. Women who attend for a smear will be managed according to their cytology (as usual) on the NHS Cervical Screening Programme. Women who test HPV positive and have not attended for a smear by the end of the study will be invited for a study colposcopy at Whipp's Cross Hospital.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Proportion of women who return a self-collected sample for HPV testing measured at the end of the study

Secondary outcome measures
1. Proportion of women who are found to have cervical intraepithelial neoplasia; Timepoint(s): End of study
2. Proportion of women who are found to test HPV positive; Timepoint(s): End of study

Overall study start date
23/11/2012

Completion date
15/04/2015

Eligibility

Key inclusion criteria
Women aged 28-64 years who are eligible for cervical screening and are at least 6 months overdue (i.e. no cervical cytology recorded in the GP records in the past 3.5 years if aged 28-49 or 5.5 years if aged women 50-64)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Planned Sample Size: 200; UK Sample Size: 200; We have estimated that with 5 GP surgeries, the sample size will be anywhere between 45 and 337. 200 women is our rough estimate.

Key exclusion criteria
1. Women unable to provide informed consent (e.g. because of learning difficulties)
2. Women whose command of English is not sufficient to obtain informed consent

3. Women in whom cervical screening is inappropriate, for example because they are pregnant or terminally ill

Date of first enrolment
22/12/2013

Date of final enrolment
05/12/2014

Locations

Countries of recruitment
United Kingdom

Study participating centre
The Blithehale Health Centre
22 Dunbridge Street
Bethnal Green
London
E2 6JA

Study participating centre
The Neaman Practice
15 Half Moon Court
London
EC1A 7HF

Study participating centre
Hoxton Surgery
12 Rushton Street
London
N1 5DR

Study participating centre
Chrisp Street Health Centre
100 Chrisp Street
London
E14 6PG

Study participating centre

Amersham Vale Training Practice Suite 5 – Waldron Health Centre
Amersham Vale
New Cross
London
SE14 6LD

Study participating centre
Kingfisher Medical Centre
Staunton Street
Deptford
SE8 5DA

Sponsor information

Organisation
Queen Mary University of London (UK)

Sponsor details
R&D Office, Queen Mary University of London
Barts & London School of Medicine The QMI building
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; Grant Codes: C8162/A10406

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

Intention to publish date

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Anita Lim (a.lim@qmul.ac.uk).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2017		Yes	No
Participant information sheet	version v2	16/10/2013	07/07/2017	No	Yes
HRA research summary			28/06/2023	No	No