

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

Submission date 21/11/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 21/11/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 07/07/2017	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English Summary

<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

Contact name

Dr Anita Lim

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Contact details

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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 hypothesis

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

Condition

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

Overall study end date

15/04/2015

Eligibility

Participant 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.

Participant 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

Recruitment start date

22/12/2013

Recruitment end date

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

Chrip Street Health Centre

100 Chrip 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