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Comparing different ways to take self-samples for HPV testing for cervical screening

Submission date 18/04/2016	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/04/2016	**Overall study status** Ongoing	
Last Edited 25/08/2021	**Condition category** Cancer	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-comparing-a-urine-sample-and-different-ways-of-collecting-and-transporting-vaginal-samples

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
20833

Study information

Scientific Title
A randomised-assignment comparison study of the performance of self-collected vaginal samples for Human Papillomavirus (HPV) testing when transported under wet or dry conditions, using different collecting devices

Study objectives
The aim of this study is to compare wet Dacron and dry flocked swabs and two commercially-designed devices to take a 'self-sample' for HPV testing

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised; Interventional; Design type: Screening, Imaging

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

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
Specialty: Cancer, Primary sub-specialty: Gynae; UKCRC code/ Disease:

Interventions
Current interventions as of 08/09/2017:
Before their colposcopy examination women, who have signed a consent form to take part, will firstly be asked to provide a sample of urine using a Colli-Pee collection kit. They will then be asked to take two self-samples, either:

1. Swabs (like cotton buds) - one taken with a Dacron swab and placed into a liquid specimen transport medium and one with a dry flocked swab and transported as a dry sample. The order in

which samples are taken is randomised to avoid bias.
or
2. Qvintip and HerSwab self-test kits. This involves women taking a sample with a HerSwab collection device and a sample taken with a Qvintip device. Once again sample order will be randomised. 300 women will be put into each group and given an illustrated instruction sheet. They will also be asked to fill in a short questionnaire about how easy or difficult they found taking each sample. Any smear and biopsy results from the colposcopy, and over the following 9 months or so, will be collected from hospital records. Self-samples will be taken to the Centre for Cancer Prevention. HPV results will be not given to the woman or her doctor as we do not know how reliable they are for clinical care.
They may continue to take the cervico-vaginal samples even if they cannot provide a urine sample.

There is no active follow-up of participants. Passive follow-up of the collection of histology and cytology results will take place. Taking part in the study will not affect routine colposcopy care.

Previous interventions:
Before their colposcopy examination women, who have signed a consent form to take part, will be asked to take two self-samples, either:

1. Swabs (like cotton buds) - one taken with a Dacron swab and placed into a liquid specimen transport medium and one with a dry flocked swab and transported as a dry sample. The order in which samples are taken is randomised to avoid bias.

or

2. Qvintip and HerSwab self-test kits. This involves women taking a sample with a HerSwab collection device and a sample taken with a Qvintip device. Once again sample order will be randomised. 300 women will be put into each group and given an illustrated instruction sheet. They will also be asked to fill in a short questionnaire about how easy or difficult they found taking each sample. Any smear and biopsy results from the colposcopy, and over the following 9 months or so, will be collected from hospital records. Self-samples will be taken to the Centre for Cancer Prevention. HPV results will be not given to the woman or her doctor as we do not know how reliable they are for clinical care.

There is no active follow-up of participants. Passive follow-up of the collection of histology and cytology results will take place. Taking part in the study will not affect routine colposcopy care.

Intervention Type
Other

Primary outcome measure
1. The total amount of nucleic acid in the samples (including RNA)
2. Quantification of amplifiable human genomic DNA
3. Estimation of the viral load of HPV16 in the samples
4. Validated HPV platforms which will give quantifiable measures of HPV with some degree of typing

Secondary outcome measures
Histological and cytological outcomes and total scores allocated by women to each test on the acceptability questionnaire

Overall study start date
15/03/2016

Completion date
01/12/2027

Eligibility

Key inclusion criteria
1. Women attending for colposcopic examination at the Royal London Hospital colposcopy clinic
2. Referred as a consequence of abnormal screening cytology and/or positive HPV result
3. Who have a cervix
4. Who give written informed consent
5. Aged 18 years and above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Planned Sample Size: 600; UK Sample Size: 600

Key exclusion criteria
1. Pregnancy
2. History of excisional or ablative treatment for CIN within the last three years

Date of first enrolment
22/04/2016

Date of final enrolment
16/08/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Royal London Hospital
Bart's Health Colposcopy Service
Colposcopy Unit
Gynaecology Outpatients
Women's Centre
8th Floor
Whitechapel Road
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Bart's Health NHS Trust

Sponsor details
Dr Mays Jawad
Research & Development Governance Operations Manager
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Government

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
The aim would be to publish in a peer reviewed journal by 31/12/2019. There would also be the intention to present the data at either the 33rd International Papillomavirus Conference March 2020 or EUROGIN - European Research Organisation on Genital Infection and Neoplasia conference in December 2019.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date