

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

Submission date 18/04/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/04/2016	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/08/2021	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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

Contact name

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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:

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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
Joint Research Management Office
5 Walden Street
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United Kingdom
E1 2EF

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