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Two self-sampling methods (Vaginal dry swabs vs. FTA-elute cartridge) for HPV detection.

Submission date
24/04/2015

Recruitment status
No longer recruiting

Registration date
22/05/2015

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Human papillomavirus (HPV) detection is useful for cervical cancer screening. We are carrying out a study of 130 women to compare the acceptability and analytic performance of two dry storage and transportation devices, FTA elute cartridge and Vaginal Dry Swabs for HPV testing. Our goal is to simplify the method of sampling and transport for HPV detection. The study's findings should help to improve women's well-being by using the most cost-effective strategy for HPV screening. If self-collection using simple vaginal dry swabs proves to be as sensitive as the standard HPV testing (sample collected by a physician using a liquid medium) or the actual new alternatives, the FTA cartridge, it will contribute to the development and validation of this method for HPV screening.

Who can participate?
Women, aged at least 30 years from the colposcopy clinic of the Geneva University Hospitals, Switzerland.

What does the study involve?
Over a period of one year, participants are invited to perform two self-sampling (using the FTA card and the vaginal dry swab). Randomization will determine the sequence of the two tests, avoiding potential bias that may advantage the "first" test. All specimens are tested for the same pathogens (HR-HPV) using the same diagnostic test (Real-time PCR). At the end of the study, we compare the agreement between collection methods in terms of HPV positivity.

What are the possible benefits and risks of participating?
There will be no immediate direct benefit to those taking part. But there should be benefits to women worldwide, particularly in low resource countries, because the results of the study may influence how HPV screening will be carried out in the future. There are no risks inherent to this study.

Where is the study run from?
University Hospitals of Geneva (Switzerland)

When is study starting and how long is it expected to run for?
December 2013 to March 2015

Who is funding the study?
Funding has been provided by the University Hospitals of Geneva (Projets Recherche & Développement (PRD)).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Randomized comparison of two self-sampling methods (Vaginal dry swabs vs. FTA-elute cartridge) for HPV detection.

Study objectives

Dry storage devices (FTA elute cartridge and Vaginal Dry Swabs) for self-sampling are well accepted among women and are equivalent to physician's collected sample using specimen transport medium.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cantonal Human Research Ethics Commission of Geneva, 17/.02/2014, ref: CCER, CER: 14-011

Study design
Women will be invited to perform two self-sampling (FTA and v-DRY) in our colposcopy clinic in Geneva. All specimens will be tested for the same pathogens (HR-HPV) using the same diagnostic test (Real-time PCR).

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Cervical pre-cancer and cancer.

Interventions
Women were invited to perform two self-sampling (FTA and v-DRY). Randomization of the sequence of the two self-HPV tests was done to avoid potential bias that may advantage the “first” test.
The research nurse would then give oral instructions to the patients. For specimen collection, participants were instructed to wash their hands before the procedure. Each participant received a package containing specimen collection kit. The brush used for self-collection using the FTA cartridge was the Rovers Viva-brush (Rovers Medical Devices B.V., Oss, The Netherlands), whereas the swab used for the self-collection in the v-DRY method was the flocked mid-turbinate swab (Copan FLOQSwabs™; Copan, Italy). Recommendations were to hold the brush/swab by the end of the handle, to insert the brush/swab into the vagina, avoiding contact with the external genitalia, until they meet resistance (at least 6 cm). Once they met resistance, they should gently turn the brush/swab three to five times. Subsequently the brush should be applied to the FTA cartridge by pressing it onto the middle of sample area indicated and then rotate de brush 3-5 times across that area. On the other hand, the swab was just inserted inside its plastic sleeve (v-DRY).

During the colposcopy consultation, the physician collected also a sample using specimen transport medium (Copan ESwab, Brescia, Italy) for HPV testing.

HPV analysis was performed using the Anyplex II HPV28 (H28) Detection test (Seegene, Seoul, South Korea).

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Agreement between collection methods in terms of HPV positivity, measured using kappa statistic and corresponding standard deviation.

Secondary outcome measures
1. Sensitivity and specificity to detect high-risk HPV using the result from the physician's collected samples as gold standard was reported, as well as, sensitivity and specificity of the three sampling methods for abnormal Pap smear. Because of the small number of high-grade squamous intraepithelial lesion (HSIL) or carcinomas in our population, we assessed sensitivity and specificity for low-grade squamous intraepithelial lesion or greater lesions (LSIL+). The two-tailed McNemar's test was used for mutual comparison of sensitivity and specificity.
2. Positive and negative predictive values to detect high-risk HPV using the physician's collected samples as gold standard
3. Positive and negative predictive values of the three sampling methods to detect high-risk HPV for abnormal Pap smear results
4. Agreement between collection methods in terms of HPV positivity, according to cytological results
Agreement between collection methods according to cytological results was measured using kappa statistic and corresponding standard deviation
5. Proportion of positive agreement (PPA) between paired FTA and Vaginal dry swabs (v-DRY) samples. The proportion of positive agreement (PPA) between paired FTA and v-DRY samples was calculated by using the following formula: 2a/(f1+g1), where a=the number of samples that were positive for HPV in both dry samples, f1=the number of samples that were positive for FTA and g1=the number of samples that were positive for v-DRY
6. Proportion of positive agreement (PPA) between paired self collection methods (combined results of FTA and v-DRY) and physician's collected sample. The proportion of positive agreement (PPA) between paired self collection methods and physician's collected samples was calculated by using the following formula: 2a/(f1+g1), where a=the number of samples that were positive for HPV in both samples, f1=the number of samples that were positive for the self-collection methods and g1=the number of samples that were positive for the physician's collected sample
7. Women's preference regarding the collection methods. Women completed a self-administered questionnaire

Data will be analyzed with a statistical analysis software package (StataCorp.2013., Stata Statistical Software: Release 13. College Station, TX, USA).

Overall study start date
01/12/2013

Completion date
01/03/2015

Eligibility

Key inclusion criteria
1. At least 30 years old
2. Attending colposcopy clinic
3. Understands study procedures and accepts voluntarily to participate by signing the informed consent form (ICF)

Participant type(s)
Patient

Age group
Adult

Lower age limit
30 Years

Sex
Female

Target number of participants
130

Key exclusion criteria
1. Pregnancy
2. Previous Hysterectomy
3. Virgin
4. Not able to comply with protocol study

Date of first enrolment
01/03/2014

Date of final enrolment
28/02/2016

Locations

Countries of recruitment
Switzerland

Study participating centre

Geneva University Hospitals
Boulevard de la Cluse 30
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Sponsor information

Organisation
Geneva University Hospitals

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Government

Funder Name
Research Projects for Development (Projets Recherche & Développement) (PRD) - HUG

Results and Publications

Publication and dissemination plan
We intend to publish all the results from this study in an international scientific journal by the end of the year 2015.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/12/2015		Yes	No
Protocol (other)			14/06/2023	No	No