

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

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| <b>Submission date</b><br>24/04/2015   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>22/05/2015 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>14/06/2023       | <b>Condition category</b><br>Cancer               | <input type="checkbox"/> 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

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Protocol serial number

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

## **Study type(s)**

Prevention

## **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(s)**

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

### **Key secondary outcome(s)**

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).

### **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

30 years

**Sex**

Female

**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

Genève

Switzerland

1205

**Sponsor information****Organisation**

Geneva University Hospitals

**ROR**

<https://ror.org/01m1pv723>

# Funder(s)

## Funder type

Government

## Funder Name

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

# Results and Publications

## 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? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results | 02/12/2015   |            | Yes            | No              |
| <a href="#">Protocol (other)</a> |         |              | 14/06/2023 | No             | No              |