

# Validation study of vaginal dry swabs using the Xpert HPV test for human papillomavirus diagnosis

<b>Submission date</b> 02/10/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 06/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 07/11/2023	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Cervical screening is a method of preventing cancer by detecting and treating early abnormalities which, if left untreated, could lead to cervical cancer. Infection with some high-risk types of human papilloma virus (HPV) can increase the risk of developing cervical cancer. Evidence from several studies has shown that testing for HPV infection is more effective at preventing cervical cancer than cytology (taking a sample of cervical cells). The Xpert HPV test is a way to rapidly detect high-risk HPV infection. It is performed using a special liquid medium (PreservCyt). However, storage of the liquid is not practical. Our aim is to evaluate the possibility of women self-sampling using dry swabs for HPV detection with the Xpert HPV test.

### Who can participate?

Women age over 18 attending the colposcopy clinic.

### What does the study involve?

Each patient is asked to provide two samples for HPV testing. They are first asked to perform self-sampling using a dry swab and then the doctor or nurse collects a second sample using a liquid medium. All samples are tested for high-risk HPV using the same test (Xpert HPV test). Patients later obtain their HPV test results and are managed accordingly.

### What are the possible benefits and risks of participating?

Participating in the study has no direct and immediate benefits. However, if we prove that dry swabs are as good as the standard method for HPV detection using the Xpert HPV, it will help with cervical screening in developing countries by reducing the need for repeated visits. It will also help to increase participation in screening programs in developed countries by giving women alternatives for screening that might be more adapted to their busy schedule or budget. This study will not have any risks for the participants' health.

### Where is the study run from?

University Hospitals of Geneva (Switzerland).

When is the study starting and how long is it expected to run for?  
September 2014 to October 2015.

Who is funding the study?  
Hôpitaux Universitaires de Genève (Switzerland).

Who is the main contact?  
Dr Rosa Catarino

## Contact information

**Type(s)**  
Public

**Contact name**  
Dr Rosa Catarino

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**Contact details**  
Boulevard de la Cluse 30  
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1205

## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Protocol serial number**  
N/A

## Study information

**Scientific Title**  
Validation study of vaginal dry swabs using the Xpert HPV test for human papillomavirus diagnosis

**Study objectives**  
Dry swabs performance is equivalent to the performance of standard physician-collected samples with swab immediately immersed in PreservCyt for HPV detection using the Xpert HPV test.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

**Study design**

Observational

**Primary study design**

Observational

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Human papillomavirus infection

**Interventions**

Women will be invited to perform two samplings for HPV testing. Women will firstly be asked to perform a Self-HPV using a dry swab (S-DRY) and then the physician or nurse will perform a cervical collection immersed in PreservCyt (dr-WET). All specimens will be tested for the same pathogens (HR-HPV) using the same diagnostic test (Xpert HPV). Later, the remaining sample immersed in PreservCyt will be tested for HPV DNA using cobas HPV test.

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

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**Primary outcome(s)**

Agreement between the S-DRY and dr-WET samples concerning HPV types and HPV positivity will be measured using the kappa statistic ( $\kappa$ ).

**Key secondary outcome(s)**

1. Sensitivity and specificity will be calculated for each method, using the cobas HPV test results as reference. Cytological results will also be used as a reference.
2. We will also analyze invalid test results using the Xpert HPV test and the delay between self collection and HPV analysis

**Completion date**

31/10/2015

**Eligibility****Key inclusion criteria**

1. Age  $\geq 18$  years
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**

18 years

**Sex**

Female

**Total final enrolment**

150

**Key exclusion criteria**

1. Pregnancy
2. Previous hysterectomy

**Date of first enrolment**

04/03/2015

**Date of final enrolment**

31/10/2015

**Locations****Countries of recruitment**

Switzerland

**Study participating centre**

University Hospitals of Geneva

Geneva

Switzerland

1205

**Sponsor information****Organisation**

University Hospitals of Geneva (Switzerland)

ROR

https://ror.org/01m1pv723

## Funder(s)

### Funder type

Hospital/treatment centre

### Funder Name

Hôpitaux Universitaires de Genève

### Alternative Name(s)

Geneva University Hospitals, HUG

### Funding Body Type

Government organisation

### Funding Body Subtype

Local government

### Location

Switzerland

## 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	27/07/2017	23/01/2019	Yes	No
<a href="#">Protocol (other)</a>		27/07/2017	07/11/2023	No	No