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

Submission date
02/10/2015

Recruitment status
No longer recruiting

Registration date
06/10/2015

Overall study status
Completed

Last Edited
07/11/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
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)
The Cantonal Human Research Ethics Commission of Geneva (CCER), 30/11/2014, CER: 14-228

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)
-

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 (κ).

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 ≥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?
Results article	results	27/07/2017	23/01/2019	Yes	No
Protocol (other)		27/07/2017	07/11/2023	No	No