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Feasibility of a single-visit approach using rapid HPV-testing in Cameroon

Submission date 13/09/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 01/11/2015	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 30/12/2022	**Condition category** Cancer	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Human papilloma viruses (HPV) are a family of viruses which affect the skin and moist membranes (mucosa) lining the body. HPVs are very common viruses, and will affect most people at some point in their lives. These viruses easily spread from person to person via skin-to-skin contact or contact during sex. There are over 100 different types of HPV, with more than 40 affecting the genital area. Some types of HPV, known as high risk types, have been linked to the development of abnormal cells in the cervix. If left untreated, this can greatly increase a woman' s risk of developing cervical cancer. Studies have shown that a large proportion of new cervical cancer cases are found in less developed countries. A possible reason for this is that women in these countries do not have access to vaccinations or a structured screening programme testing for the abnormal cells (Pap smear), due to high costs and a lack of trained healthcare professionals. Rapid HPV self-testing is where the woman herself is able to take a sample which can be tested. This has the advantage of being very inexpensive, and can reach a lot more women, especially in rural areas. The aim of this study is to test how practical and safe self-testing for HPV can be at preventing cervical cancer.

Who can participate?
Healthy women between 30 and 49 years old, with a good understanding of the HPV screening procedure

What does the study involve?
Women are given swabs so that they can take samples to be tested for HPV. Women who have a negative HPV test (absence of a HPV type that is linked to cervical cancer) are provided with reassurance and asked to repeat the test in 5 to 10 years. Women who have a positive HPV test (presence of a HPV type that is linked to cervical cancer) are invited for a visual inspection, where digital photographs of the cervix are taken and reviewed by experts. If the result is abnormal, then the women are offered therapy.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Dschang District Hospital (Cameroon)

When is the study starting and how long is it expected to run for?
June 2014 to August 2016

Who is funding the study?
1. Geneva University Hospitals (Switzerland)
2. National Fight Against Cancer Committee (France)

Who is the main contact?
Prof. Patrick Petignat

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15-068

Study information

Scientific Title
Cervical cancer screening in Cameroon: feasibility of a single-visit approach using rapid HPV-testing

Study objectives
Feasibility of a single-visit approach using rapid HPV-testing in low resource setting as Cameroon.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Commission Cantonale d'Ethique de la Recherche (CCER) de Genève, 16/06/2015, ref: 15-068
2. National Ethics Committee for Human Health Research (Cameroon), 27/02/2015, ref: 2015/02/559/CE/CNERSH/SP

Study design
Prospective non-randomised study

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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Cervical cancer

Interventions
All women will take an HPV test. HPV-negative women will be reassured and counseled to repeat the test in 5 to 10 years. HPV-positive women with normal VIA/VILI test will undergo an endocervical curettage (ECC) and cytology to exclude presence of occult disease. HPV-positive women with abnormal VIA/VILI test will undergo a biopsy of abnormal area followed by therapy with cold coagulation. Pictures of the cervix and abnormal areas will be taken to assure a control of quality.

Intervention Type
Other

Primary outcome measure
Current primary outcome measures as of 26/09/2017:
The feasibility of HPV cervical cancer screen-and-treat approach in a low-resource context, assessed by measuring the number of women who took part in the screening campaign and the relative number of drop-outs and invalid test results at baseline

Previous primary outcome measures:
The prevalence of HPV infection and cervical pre-cancer and cancer will be determined among Cameroonian women at baseline, 6 months and 1 year

Secondary outcome measures
Current secondary outcome measures as of 26/09/2017:
1. The prevalence of HPV infection, cervical pre-cancer and cancer among Cameroonian women, determined using rapid HPV testing, cytology and histology at baseline
2. Performance of VIA/VILI and HPV16/18/45 genotyping for detection of high grade cervical lesions, determined using the kappa statistic at baseline
3. The association of risk factors leading to high-risk HPV infection and cervical pre-cancer and cancer, determined using calculated odds ratio (OR) at baseline

Previous secondary outcome measures:
1. To compare the agreement between histology and VIA results as well as cervical picture and VIA results, measured using the kappa statistic at 6 and 12 months
2. To evaluate the association of risk factors leading to high-risk HPV infection and promoting cervical neoplasia using calculated odds ratio (OR) at 6 months follow up
3. Verification as to whether HPV self-testing alone is an accurate test and can reduce the need for physician-cervical sampling, measured at 6 months follow up
4. HPV clearance is measured at 6 and 12 months

Overall study start date
12/06/2014

Completion date
31/08/2016

Eligibility

Key inclusion criteria
1. Women aged 30-49
2. Understanding of study procedures

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
1000

Key exclusion criteria
1. Pregnancy
2. Previous hysterectomy
3. Conditions that can interfere with visualization of the cervix (menstruation)
4. Women who not able to comply with protocol study

Date of first enrolment
08/07/2015

Date of final enrolment
04/09/2015

Locations

Countries of recruitment
Cameroon

Study participating centre
Dschang District Hospital
Dschang
Cameroon
-

Sponsor information

Organisation
Geneva University Hospitals (Hôpitaux Universitaires de Genève)

Sponsor details
Boulevard de la Cluse 30
Genève
Switzerland
1205

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01m1pv723

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Geneva University Hospitals

Alternative Name(s)
Geneva University Hospitals, HUG

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Switzerland

Funder Name
National Fight Against Cancer Committee

Results and Publications

Publication and dissemination plan

Intention to publish date

Individual participant data (IPD) sharing plan
The dataset is securely stored in the online database SecuTrial. As only the selected study investigators have access to it, the database will not be available to the public.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2017		Yes	No
Basic results		19/09/2017	19/10/2017	No	No
Other publications		07/01/2017	30/12/2022	Yes	No