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Advances in Screening and Prevention In REproductive Cancers (ASPIRE): A community based trial to determine optimal cervical cancer screening in a low-resource setting

Submission date
20/02/2014

Recruitment status
No longer recruiting

Registration date
17/03/2014

Overall study status
Completed

Last Edited
12/04/2019

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
Cervical cancer is still a public health burden, particularly in developing countries such as sub-Saharan Africa where organized screening programs do not exist and cervical cancer rates are high. As a result, other screening approaches such as visual inspection with acetic acid (VIA) are the standard approach in such regions. It is now known that long-term infection with high-risk human papillomavirus (HPV) necessary leads to cervical cancer and evidence is showing that HPV testing is a potential, safe and effective alternative to cytology testing (the Pap smear). This study is comparing HPV self-collection with VIA in women from Kisenyi, Uganda.

Who can participate?
Women between the ages of 30-65 who live and or work in Kisenyi, Uganda.

What does the study involve?
After providing consent, women will be asked to complete a confidential survey by a community outreach worker. Women will be provided with information about the benefits of cervical cancer screening, and will be encouraged to attend for routine preventive health care at the Kisenyi Health Centre. Women will then be randomly allocated to one of two groups: to collect their own HPV sample or to attend Kisenyi Health Unit for VIA screening.
Women in the HPV self-collection group will be taught how to self-collect an HPV sample and then provide the sample to the outreach worker right after the survey. Outreach workers will arrange to provide results to women in 2 weeks. They will also be offered testing for other sexually transmitted infections, and treatment will be offered as needed. Women found to be positive for HPV will be provided with further information and counselling about having HPV, and will be invited to attend an assessment at Kisenyi Health Unit for a pelvic exam to see if there are any abnormalities.
Women in the VIA group will be instructed to attend Kisenyi Health Unit to have VIA. This will involve a pelvic examination by a trained nurse-midwife. They will also be offered testing for other sexually transmitted infections, and treatment will be offered as needed. If the VIA is

positive for pre-cancer cells standard treatment with cryotherapy will be offered immediately. After a year has passed, all women in the study will be asked to return for a follow-up visit. At this visit, they will be invited to complete voluntary (optional) surveys and have a pelvic exam, which will include an HPV test and a Pap test and other sexually transmitted infection testing will be offered.

What are the possible benefits and risks of participating?
There are no known risks regarding self-collecting the HPV specimen. The pelvic exams or VIA procedures may be mildly uncomfortable. Women who participate may or may not personally benefit by participating. Women in the study will have access to HPV and cervical cancer screening and treatment (if needed). Participants may contribute new information that may benefit women in the future.

Where is the study run from?
The study takes place in Kisenyi, Uganda. Follow-up visits will occur at the Kisenyi Health Unit and the Mulago Hospital in Kampala and if further treatment is needed. The study is run in collaboration with researchers from the University of British Columbia (UBC) in Vancouver, Canada, and researchers from Makarere University, Uganda.

When is study starting and how long is it expected to run for?
This study is expected to begin in March 2014 and run through till the end of March 2015. Recruitment is expected will be open for approximately 6 months. The remainder of the study period will be the follow-up.

Who is funding the study?
Martha Piper Foundation, UBC Foundation, BC Centre for Disease Control (BCCDC) Foundation and the Womens Health Research Institute in Vancouver, Canada.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02029794

Secondary identifying numbers
H13-02627

Study information

Scientific Title
ASPIRE Pilot: Determining an optimal cervical cancer screening paradigm in a low-resource setting: A community-based pilot randomized controlled trial comparing self-collected HPV testing with visual inspection with acetic acid (VIA) screening in Kampala, Uganda

Acronym
ASPIRE Pilot RCT

Study objectives
It is hypothesized that self-collection for HPV testing is a feasible and effective option for cervical cancer screening, compared to the current standard of care (VIA); providing enough evidence to proceed with implementation of a self-collection based screening program in this population.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of British Columbia Clinical Research Ethics Board (Vancouver Canada), H13-02627
2. Makarere University, Uganda Research Ethics Board 2011-170

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Screening

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

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

Interventions
The study will involve 600 women who will be randomly assigned to either HPV self-collection or VIA testing.
1. Women in the HPV self-collection group will be taught how to self-collect an HPV sample and samples will be provided to an outreach worker. Participants will also be offered testing for other sexually transmitted infections. Results will be available within 2 weeks. Participants found to be positive for HPV will be provided with further information and counselling about HPV, and invited to attend an assessment at Kisenyi Health Unit for a pelvic exam for further assessment.

2. Women assigned to the VIA group will attend the procedure at Kisenyi Health Unit. The procedure will involve a pelvic examination by a trained nurse-midwife. They will also be offered testing for other sexually transmitted infections, and treatment will be offered as needed. If the VIA is positive for pre-cancer cells standard treatment with cryotherapy will be offered immediately.

All participants will be asked to return for a follow-up visit 12 months after the baseline visit. At this visit, they will be invited to complete optional surveys and have a pelvic exam, which will include an HPV test and a Pap test and other sexually transmitted infection testing will be offered.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Development of cervical intraepithelial neoplasia (<CIN 1 vs >=CIN2) compared between the two groups.

Secondary outcome measures
1. The proportion of women who provide a self-collected specimen or who attended VIA will be compared
2. Rates of CIN (>CIN3 vs. <CIN2) at 12 months will be compared between the two groups
3. Proportion of women who complete all follow-up assessments and treatment will be compared between the two groups
4. Proportion of women who may experience adverse events during participation will be compared between the two groups

Overall study start date
15/03/2014

Completion date
31/03/2015

Eligibility

Key inclusion criteria
1. Women aged 30-65
2. Live and or work in Kisenyi, Uganda
3. Access to mobile telephone
4. Fluent in Luganda, Somali or English
5. Competent to provide consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
600

Key exclusion criteria
1. Known to be pregnant by self-report at study entry
2. Complete hysterectomy
3. Prior diagnosis or treatment of cervical dysplasia or cervical cancer

Date of first enrolment
15/03/2014

Date of final enrolment
31/03/2015

Locations

Countries of recruitment
Canada

Uganda

Study participating centre
655 West 12th Avenue
Vancouver
Canada
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Sponsor information

Organisation
University of British Columbia (Canada)

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Sponsor type
University/education

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Research organisation

Funder Name
The Martha Piper Foundation (Canada)

Funder Name
UBC Foundation (Canada)

Funder Name
British Columbia Centre for Disease Control (BCCDC) (Canada)

Funder Name
The Womens Health Research Institute, Vancouver (Canada)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	preliminary results	01/10/2015	12/04/2019	Yes	No