

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	☐ Prospectively registered ☐ Protocol
Registration date 17/03/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 12/04/2019	Condition category Cancer	☐ 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 Makerere 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?

Dr Gina Ogilvie
gina.ogilvie@bccdc.ca

Contact information

Type(s)

Scientific

Contact name

Dr Gina Ogilvie

Contact details

655 West 12th Avenue
Vancouver
Canada
V5Z 4R4
+1 604-707-2422
Gina.ogilvie@bccdc.ca

Additional identifiers

ClinicalTrials.gov (NCT)

NCT02029794

Protocol serial number

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. Makerere University, Uganda Research Ethics Board 2011-170

Primary study design

Interventional

Study design

Randomized controlled trial

Study type(s)

Screening

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

V5Z 4R4

Sponsor information**Organisation**

University of British Columbia (Canada)

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

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