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Integrated cervical cancer screening in Mayuge district Uganda (ASPIRE Mayuge)

Submission date
14/05/2019

Recruitment status
No longer recruiting

Registration date
17/05/2019

Overall study status
Completed

Last Edited
17/12/2024

Condition category
Cancer

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

Plain English summary of protocol

Background and study aim
Cervical cancer is one of the most preventable cancers with vaccination and effective screening available, yet it still is responsible for unnecessary deaths globally. The vast majority of cases of cervical cancer occur in the developing world with sub-Saharan Africa carrying the highest burden due to poor infrastructure and competing health needs. Human papillomaviruses (HPV) are the most common sexually transmitted infections (STI) globally. There are two types of HPV (types 16 and 18) that are considered to be "high risk" (HR-HPV) because they cause cervical cancers and pre-cancerous cervical lesions. If detected early through cervical cancer screening tests, pre-cancerous cervical lesions can be treated before they become invasive. There are three primary screening approaches to cervical cancer screening in use globally: Pap smears, HPV-DNA testing, and Visual inspection with acetic acid (VIA). A Pap smear is a procedure where a health professional takes a sample of cells from a woman's cervix and then sends the sample to a lab to test for abnormalities. This is an inefficient screening tool in LMIC as it requires complex infrastructure, trained staff, and clinical sites to test the specimens. An HPV-DNA test involves obtaining a sample by swabbing the vaginal canal and testing the sample to detect high-risk types of HPV. Although this method still relies on infrastructure and trained personnel, samples can be self-collected. VIA involves a practitioner applying acetic acid to the cervix during a speculum exam. The practitioner then inspects and classifies lesions as 'screen positive' (white), 'screen negative' (non-white), or suspicious (ulcerated or necrotic). ‘Screen positive’ lesions are treated immediately with cryotherapy, (known as ‘see and treat’). ‘Suspicious’ lesions undergo colposcopy for definitive diagnosis and treatment. VIA is the current recommended approach for cervical cancer screening in low resource settings without access to HR-HPV testing, by the WHO. It can be conducted by mid-level practitioners, can be locally based, and requires little infrastructure or laboratory support beyond training for introduction.

The ASPIRE intervention includes participant self-collection of a vaginal sample for HPV testing. The primary objective of this study is to compare cervical cancer screening follow-up using two implementation approaches for self-collected HPV testing in a rural, low-resource setting: 1) community health workers recruiting women door-to-door and 2) community health meetings. Our primary outcome for each arm will be the proportion of total screened women who complete VIA follow-up and treatment after testing positive for high-risk HPV type.

Who can participate?
Women with no hysterectomy or cervical cancer history, between the ages of 25 and 49, who have not previously been screened and treated for cervical cancer and who have provided written consent.

What does the study involve?
Women will be recruited either door-to-door or at a community health day to participate in the study. A community health worker will educate women and offer them the opportunity to screen for cervical cancer through the self-collected screening method. Women who are HPV positive will be referred for further testing (VIA) and treatment if necessary.

What are the possible benefits and risks of participating?
Participants will be educated about the benefits of cervical cancer screening and its cause (HPV). They will be able to access HPV and cervical cancer screening and treatment if needed. They will also benefit from being tested and treated for chlamydia and gonorrhoea if they have it. Findings from this study will also help identify the best method for integrating cervical cancer screening into rural communities throughout Uganda.
There are no known risks to the self-collecting the HPV specimen. It may feel mildly uncomfortable but it should not be painful. The VIA involves a pelvic exam, this can be uncomfortable but should not be painful. If participants require treatment of a pre-cancer lesion with cryotherapy (localized freezing of abnormal tissue on the cervix to destroy these abnormalities) this is uncomfortable and will result in vaginal discharge for a few weeks, there is a very small chance participants may develop an infection and require some medication to treat this. After a year has passed participants will be offered a pelvic examination for follow-up at which time a biopsy will be done. This may hurt for less than a minute and may cause vaginal spotting for a few hours.

Where is the study run from?
1. Women's Health Research Institute (Vancouver, Canada)
2. Uganda Cancer Institute (Kampala, Uganda)
3. Kigandalo Health Centre (Kigandalo, Uganda)
4. Mayuge Health Centre (Mayuge, Uganda)
5. Buwaisawa Health Centre (Buwaisawa, Uganda)

When is the study starting and how long is it expected to run for?
January 2018 to December 2021

Who is funding the study?
Canadian Institutes of Health Research (CIHR)

Who is the main contact?
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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
NCT04000503

Protocol serial number
F15-00496CIHR

Study information

Scientific Title
Integrated cervical cancer screening in Mayuge district Uganda (ASPIRE Mayuge): a pragmatic cluster randomized control trial

Acronym
ASPIRE Mayuge

Study objectives
More women will receive screening via the community health meeting but the engagement to care (i.e., visual inspection with acetic acid-our main outcome) will be less compared to the door-to-door arm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/05/2018, University of British Columbia Children's & Women's Research Ethics Board (A2-141A, 950 West 28th Avenue, Vancouver, BC V5Z 4H4; cwreb@bcchr.ubc.ca; (604) 875-3103), ref: H17-03332

Study design
Multicentre pragmatic cluster randomized controlled trial

Primary study design
Interventional

Study type(s)
Screening

Health condition(s) or problem(s) studied
Cervical cancer and cervical pre-cancer

Interventions
The purpose of this randomized control trial is to test the effectiveness of cervical cancer screening follow-up completion using two implementation approaches for self-collected HPV (human papilloma virus) testing in a rural, low-resource setting: 1) community health workers recruiting women door-to-door and 2) community health workers recruiting women at community health meetings. This study will also help to further understand how current patient referral systems are working between health facilities, patient and provider preferences for integrated care and health system related barriers to integrated cervical cancer screening.

Clusters will be stratified by study region and randomized using a computer-based system to one of two treatment arms in a 1:1 allocation sequence.

Arm 1: Women will be educated and offered self-collection cervical cancer screening, STI screening, and education on HIV by a community health worker via door-to-door recruitment.
Arm 2: Women will be educated and offered self-collection cervical cancer screening, STI screening, and education on HIV by a community health worker via community health meeting recruitment.
Women who test positive for high-risk HPV types will be referred to a designated health centre for VIA follow-up screening and treatment if indicated.

Intervention Type
Mixed

Primary outcome(s)
The difference in the rate of follow-up care for women who test positive for HR-HPV types out of all women screened in each trial arm. This will include the total number of women who completed self-collection cervical cancer screening at baseline and the proportion of women who complete VIA follow-up and treatment after testing positive for high-risk HPV type at endline (two weeks).

Key secondary outcome(s))
1. HPV prevalence at baseline: Total number of women who test positive for HPV out of the total number of samples obtained.
2. STI-HPV co-infection rate (Gonorrhea, Syphilis, etc.) at baseline:
2.1 Total number of women who test positive for STIs out of total number of women who test positive for HPV
2.2 Total number of women who test negative for STIs out of total number of women who test positive for HPV
2.3 Total number of women who test positive for STIs out of total number of women who test negative for HPV
2.4 Total number of women who test negative for STIs out of total number of women who test negative for HPV.
3. HPV and co-morbid conditions at baseline: Association (adjusted OR) estimated between HPV and HIV; other STIs.
4. Health system related challenges to women accessing integrated care in communities and facilities:
4.1 The number of HPV+ women who received VIA/treatment at endline out of the number of

women referred for VIA/Treatment at baseline
4.2 The number of HPV+ women who did not receive VIA/treatment at endline out of the number of women referred for VIA/Treatment at baseline. Reasons for attending or not attending follow-up will be identified through surveys at endline.
5. Identify differences and challenges in treatment outcomes for WLWHA: risk difference in treatment follow-up attendance between WLWHA vs. non-HIV participants at endline.

Other outcomes:
6. Cost and feasibility collected through surveys at the local health centre and by review of the national stores pricing for all consumables required for the screening and follow-up program. Program costs will be collected through review of the study related budget and receipts and time to task variables collected through clinical observation and study process documentation.
7. Determinants of successful training and capacity building of the health workforce, and
8. Government engagement and evidence uptake successes and challenges collected through ongoing documentation of study process and through planned interviews and FGDs with health workers and administrators at the local and national government level
9. Understand the role that men play in cervical cancer screening measured using a survey of a random selection of male partners

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Women with no previous history of hysterectomy or invasive cervical cancer
2. Aged 25-49 years old
3. Not previously been screened and treated for cervical cancer
4. Provided written informed consent

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
25 years

Upper age limit
49 years

Sex
Female

Total final enrolment
2019

Key exclusion criteria
Do not fulfil inclusion criteria.

Date of first enrolment
01/06/2019

Date of final enrolment
30/09/2021

Locations

Countries of recruitment
Canada

Uganda

Study participating centre
Uganda Cancer Institute
Kampala
Uganda
P.O. Box 3935

Study participating centre
Kigandalo Health Centre (HCIV)
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Study participating centre
Mayuge Health Centre (HCIII)
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Study participating centre
Buwaisawa Health Centre (HCIII)
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Sponsor information

Organisation
University of British Columbia

ROR
https://ror.org/03rmrcq20

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		10/04/2023	11/04/2023	Yes	No
Results article		05/02/2024	17/12/2024	Yes	No
Protocol article	protocol	31/01/2020	03/02/2020	Yes	No
Other publications	Participant experiences	15/04/2023	06/06/2024	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Preprint results		28/03/2022	30/06/2022	No	No