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Utility of visual inspection of the cervix in diagnosing early forms of cervical CANcer in HIV positive women

Submission date
08/12/2012

Recruitment status
No longer recruiting

Registration date
17/01/2013

Overall study status
Completed

Last Edited
13/07/2015

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Cervical cancer is one of the leading causes of cancer-related deaths for middle-aged women in low income countries. It is estimated that annually, 80,000 new cases and 60,000 deaths occur as a result of cervical cancer in sub Saharan Africa. However, it is a preventable and curable disease; preventable by vaccination and screening and curable if identified at an early stage. The mainstay of cervical cancer screening, cervical cytology, is not feasible in many low income countries at high risk for cervical cancer in view of the considerable financial, technical and manpower resources required for organizing such a program. Hence the adoption of Direct Visual Inspection (DVI) with Acetic acid (DVIA) and/or Lugols Iodine (DVILI) methods for cervical screening in low income countries with high cervical cancer burden because of its comparable ability to detect early precancerous lesions of the cervix, its low technology requirement and cost-effectiveness. In these same settings of high cervical cancer burden, the HIV/AIDS pandemic has overwhelmed the health care systems and had an enormous impact on women, particularly those of reproductive age. Several studies have shown that HIV-infected women have an increased risk for the precursors to cervical cancer, known as human papillomavirus (HPV)-associated cervical intraepithelial lesions. With the introduction of more effective antiretroviral (ARV) therapy to treat HIV, the spectrum of disease in the AIDS epidemic has been shifting. It is projected that 20 - 40% of HIV infected individuals will be diagnosed with cancer, including cervical cancer. As a result of the ARV drug scale up, increasing numbers of women are linked to antiretroviral therapy treatment programs that have the potential to improve their lifespan. At present, DVIA is being used to diagnose early forms of cervical cancer in HIV positive women. However considering the poor detection rate of other diseases like tuberculosis using proven tools in HIV positive people, perhaps DVIA will be less effective in women infected with HIV. Until now, no randomised controlled studies (a type of study design) have evaluated how sensitive DVIA will be in diagnosing early forms of cervical cancer in women living with HIV.
The objective of this study is to determine how accurate DVIA is in diagnosing early forms of cervical cancer using cytology as the gold standard.

Who can participate?
HIV positive women aged 18 years and above. Women who refuse to give consent or are allergic to Lugol's iodine cannot participate.

What does the study involve?
1000 participants will be recruited and will be randomly allocated to be screened with either acetic acid (500 participants) or Lugol's iodine (500 participants). All the participants will also be screened with a Pap smear.

What are the possible benefits and risks of participating?
Participants will know their HIV status as well as be screened for early forms of cancer of the cervix. HIV positive women will also be offered free comprehensive HIV services at our treatment centre. Women who test positive for early forms of cervical cancer will be sent to a service at a nearby teaching hospital where we have an arrangement with the consultant in charge. There is no known side effect of the diagnosis. However we are aware that some women may react to Lugol's iodine and we will exclude women with history of this.

Where is the study run from?
Clinical Research Centre, Nigerian Institute of Medical Research Lagos.

When is the study starting and how long is it expected to run for?
Recruitment for the study started in December 2011 and will last for 6 months. The study is expected to end in June 2012.

Who is funding the study?
Nigerian Institute of Medical Research Lagos

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

Secondary identifying numbers
NM/MRCH/12/001

Study information

Scientific Title
Effect of HIV infection on Human Papilloma Virus (HPV) distribution pattern, cervical cancer burden and diagnostic accuracy of direct visual inspection in Nigeria

Acronym
CANHIV

Study objectives
The sensitivity and specificity of Direct Visual Inspection will significantly be altered by Human Immunodeficiency Virus (HIV) infection and immunosuppression.

On 30/01/2014 the following changes were made to the trial record:
1. The overall trial start date was changed from 01/12/2012 to 01/12/2011
2. The target number of participants was changed from '500' to 'Two groups of 500'

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board, Nigerian Institute of Medical Research Lagos, February 2011, ref: IRB-10-126A

Study design
Randomised controlled open-label trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
HIV, premalignant lesion of the cervix

Interventions
Screening of premalignant conditions of the cervix using visual inspection with Direct Visual Inspection (DVI) with Acetic acid (DVIA) and/or Lugol's Iodine (DVILI).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Premalignant lesion of the cervix

Secondary outcome measures
High-risk HPV types

Overall study start date
01/12/2011

Completion date
30/06/2013

Eligibility

Key inclusion criteria
1. Nigerian
2. Female
3. Aged 18 years or over
4. Known HIV status

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Two groups of 500

Key exclusion criteria

1. Known reaction to Lugol's iodine
2. Refusal to do HIV test
3. Overt cancer of the cervix

Date of first enrolment
01/12/2011

Date of final enrolment
30/06/2012

Locations

Countries of recruitment
Nigeria

Study participating centre
Nigerian Institute of Medical Research
Lagos
Nigeria
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Sponsor information

Organisation
Nigerian Institute of Medical Research (Nigeria)

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Sponsor type
Government

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ROR
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Funder(s)

Funder type
Government

Funder Name
Nigerian Institute of Medical Research, Lagos (Nigeria)

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