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Human papillomavirus (HPV) vaccine in human immunodeficiency virus (HIV) positive girls and women

Submission date
22/07/2008

Recruitment status
No longer recruiting

Registration date
21/08/2008

Overall study status
Completed

Last Edited
05/04/2019

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
The Human Papilloma Virus (HPV) is a common virus that is known to have more than 100 types, and is spread through close skin contact and sexual contact. It is estimated that about 75% of women will become infected with one or more of the sexually transmitted HPV types at some point during adulthood. HPV is the virus that causes genital warts. Long-term infection with one or more of about a dozen so-called 'high-risk' sexually transmitted HPV types can lead to the development of cell changes in the cervix, called dyskaryosis, which may in turn lead to cancer of the cervix. HPV infection is responsible for the development of nearly all cases of cervical cancer. Although the widespread use of Pap testing programs has greatly reduced the incidence and death rates from cervical cancer in developed countries, the disease still kills several hundred thousand women per year worldwide. Possibly due to a decrease in the function of the immune system (the cells and substances in the body that protect the body from infection), HIV-positive women are known to have higher rates of HPV infection, and more rapid progression to cervical cancer. In addition, they are troubled by larger external genital warts that tend to be more difficult to treat. The GARDASIL™ vaccine will protect against four types of HPV; two of these types are associated with genital warts and the other two are the high-risk, cancer-causing HPV types. The GARDASIL™ studies so far have shown excellent protection against these types of HPV in healthy women and girls. To date, there are no study results for the evaluation of the safety and effectiveness of this HPV vaccine in HIV-infected persons. The aim of this study is to investigate the safety and effectiveness of giving the HPV vaccine to women infected with HIV. Many of the women over the age of about 20 will already have been exposed to HPV. However, there is research that suggests that only about 7.5% of women with HIV have ever tested positive for one of the genital wart associated types of HPV in the vaccine, and only about 16% have ever tested positive for one of the cancer associated types, suggesting that the vaccine can still offer some protection against HPV infection. We want to study whether women and girls with HIV can be protected from some or all of the types of HPV found in the vaccine.

Who can participate?
Women and girls aged 9 or older with HIV

What does the study involve?
This study involves seven to eight visits, spaced out over 2 years and 3 months. All of the study visits, except one, are scheduled on the same day as routine clinic visits for HIV care. At the start of the study participants undergo assessments (clinical labs, physical assessment, medical history, study samples). At least 3 months later, participants have additional assessments and are then vaccinated with Gardasil. Additional Gardasil vaccinations take place 2 and 6 months following the first vaccination. Participants are followed up every 6 months for up to 24 months. Study procedures include: clinical labs, cervical cytology (smear test), physical examinations, and HPV antibody serology (blood tests).

What are the possible benefits and risks of participating?
Participants may benefit from protection against some types of HPV, and therefore potential cervical cancer, as a result of being vaccinated. The knowledge gained from this study may help others who are living with HIV/AIDS in the future. As for any vaccine, vaccination with GARDASIL™ may not result in protection for all people who get it. In previous studies GARDASIL™ has been generally well tolerated.

Where is the study run from?
Women's Health Research Institute (Canada)

When is the study starting and how long is it expected to run for?
August 2008 to February 2017

Who is funding the study?
The Canadian Institute of Health Research with support from Canadian HIV Trials Network (CTN)

Who is the main contact?
Dr Deborah Money
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

MOP 86692; Health Canada File No.: 9427-U0146/5-12C

Study information

Scientific Title
A study of a human papillomavirus (HPV) virus-like particle (VLP) vaccine in a cohort of human immunodeficiency virus (HIV) positive girls and women

Study objectives
It is hypothesised that human papillomavirus (HPV) vaccination will result in a variable immune response and consequently differential vaccine effectiveness in some human immunodeficiency virus (HIV) infected girls and women, and that co-factors including T-cell immune dysfunction, age, prior HPV infection, injection drug use and ethnicity will substantially affect this response.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University of British Columbia Clinical Research Ethics Board, 18/06/2008
2. Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board, 05/09/2008
3. Women's College Research Ethics Board, 03/10/2008
4. University Health Network Research Ethics Board, 18/08/2008
5. Comité d'éthique de la recherche clinique du CHUL, 21/09/2008
6. Hamilton Health Sciences/McMaster University Faculty of Health Sciences Research Ethics Board, 18/12/2008
7. Comité d'éthique de la recherche, Centre de recherche, CHU Sainte-Justine, 21/05/2009
8. Windsor Regional Hospital Research Ethics Board, 17/09/2009
9. St. Michael's Hospital Research Ethics Board, 18/02/2009
10. McGill University Health Centre Pediatric Research Ethics Board, 17/09/2009
11. The Hospital for Sick Children Research Ethics Board, 21/09/2009
12. Children's Hospital of Eastern Ontario Research Ethics Board, 02/07/2008
13. Ottawa Hospital Research Ethics Boards, 29/10/2010

Primary study design
Observational

Study design
Prospective longitudinal cohort study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Human immunodeficiency virus, human papillomavirus

Interventions
Following informed consent/assent, subjects will have a baseline visit to assess eligibility and to obtain baseline assessments (clinical labs, physical assessment, medical history, baseline study samples). At least 3 months later, subjects will have additional assessments and then be

vaccinated with Gardasil. Additional Gardasil vaccinations will take place 2 and 6 months following the first vaccination.

Subjects will be followed every 6 months for up to 24 months. Study procedures will include: clinical labs, clinical cervical cytology, physical examinations, and study cervical cytology and HPV antibody serology.

Intervention Type
Biological/Vaccine

Primary outcome(s)
The seroresponsiveness of HIV positive girls and women to an HPV VLP quadrivalent vaccine.

Key secondary outcome(s)
1. To determine the effectiveness of an HPV quadrivalent vaccine in preventing infection and disease due to HPV 6, 11, 16 and/or 18 (types contained in vaccine)
2. To compare the level of circulating antibody to specific vaccine containing HPV genotypes in vaccinated girls and women by a proprietary assay and two independent laboratory assays
3. To determine the rate of adverse events in HIV infected girls and women given an HPV VLP vaccine compared to their baseline rate of adverse signs and symptoms

Completion date
17/02/2017

Eligibility

Key inclusion criteria
1. HIV positive
2. Aged greater than or equal to 9 years
3. Able to give fully informed consent or assent
4. Not pregnant (as determined by a negative urine pregnancy test) and willing to avoid pregnancy for the duration of the vaccination phase. Subjects at the time of the study entry must be abstinent or must be using an effective method of birth control for 30 days prior to vaccination and throughout the study up to one month following the last vaccination. Effective methods of birth control include: birth control pill, intra-uterine device (IUD), depo provera, male or female condom and spermicidal, diaphragm or sponge with spermicidal, abstinence.
5. Able to attend the clinic for all of the study visits

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
Female

Key exclusion criteria
1. Allergy to the vaccine or its components
2. Prior use of an HPV vaccine
3. Current enrolment in any clinical trial which used an investigational vaccine or drug
4. Female planning to become pregnant or likely to become pregnant prior to 30 days post-last vaccine (visit 4)
5. Any condition (physical or psychosocial) that the site investigator deems exclusionary (for example, poor prognosis, extreme immunocompromisation; an individual may be enrolled into the study after the above have resolved)

Date of first enrolment
25/11/2008

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Canada

Study participating centre
Women's Health Research Institute
Vancouver
Canada
V6H 3N1

Sponsor information

Organisation
Women's Health Research Institute (WHRI) (Canada)

ROR
https://ror.org/0455vfz21

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (Canada) (ref: MOP 86692)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), 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

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	14/09/2016		Yes	No
Results article	results	01/06/2018		Yes	No
Basic results		28/11/2016	06/12/2016	No	No