

ACTG Study A5240
Immunogenicity & Safety of a Quadrivalent HPV Vaccine in HIV-1-Infected Females

Brief Description:

Human papillomavirus (HPV) is the most common sexually transmitted disease in the United States and worldwide. There are over 90 types of HPV that infect humans. Some of these types infect the genital and anal areas where the infection causes genital and anal warts. It also causes cancer of the cervix (the opening of the uterus) in females. HPV infection may be more severe and harder to treat in people infected with HIV. The FDA has approved an HPV vaccine (called Gardasil), and it is directed against 4 types of HPV which are the most common causes of genital warts and cervical cancer. This study is the first of its kind to test the HPV vaccine in females infected with HIV.

Purpose of this Study:

This study will see if the HPV vaccine, when given in 3 separate doses, is safe and tolerable in females infected with HIV. This will be done by asking how you feel and if you had any reactions after each dose of the vaccine. The study will also check if the HPV vaccine can help the body make substances in response to the vaccination to help fight off disease caused by HPV.

Requirements to Enter Study:

- Participants must be HIV positive.
- Females ages 18 to 45.
- Any T-cell count and any viral load is acceptable.
- If you are taking antiretroviral drugs, you must be on the same combination of medicines for at least 12 weeks before the study entry visit. You do not need to be on antiretroviral drugs to be eligible for this study.
- No cervical cancer, very abnormal Pap smear, or genital warts within 180 days.
- No prior vaccinations for HPV.
- Cannot take any of the disallowed medications. Your study nurse will discuss these with you.

Other things might keep you from entering the study. Your doctor will discuss these with you if you are screened for this study.

Treatment:

Study treatment is defined as quadrivalent HPV (types 6, 11, 16, 18) recombinant vaccine, Gardasil, and will be provided to you by the study. Quadrivalent means that the vaccine is directed at four types of HPV. If you are currently taking antiretroviral drugs, you should continue taking them unless your doctor tells you otherwise. Your antiretroviral drugs will not be provided to you by the study. You must get them through your primary care provider.

Duration of Study: This study will last about one and a half years.

For more information contact:

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