

## Long-term Study of a Quadrivalent Human Papillomavirus Vaccine

D. Ferris, MD, R. Samakoses, MD, S.L. Block, MD, E. Lazcano-Ponce, MD, J.A. Restrepo, MD, K.S. Reisinger, MD, MPH, J. Mehlsen, MD, A. Chatterjee, MD, PhD, O. Iversen, MD, H.L. Sings, PhD, Q. Shou, PhD, T.A. Sausser, BS and A. Saah, MD

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### Summary:

This article describes a study that looked at both the safety and the effectiveness of the human papillomavirus (HPV), Gardasil, that protects against 4 strains of HPV. It also follows a group that does not receive the vaccine in order to have good comparison for both safety and effectiveness.

### Article Details:

Researchers studied the long-term signs that the vaccines was effective for the 4 strains of HPV (6, 11, 16, and 18) that the vaccine is meant to prevent. They also studied how well the vaccine was able to prevent infection with these strains of HPV. In order to test how effective the vaccines was, the researchers looked at 2 groups. One group, they called an Early Vaccination Group (EVG), children who were given on-time (by age 11-12) doses at 0, 2, and 6 months, and a Catch-up Vaccination Group (CVG), of children who were give a placebo at those same periods, and the actual vaccine at months 30, 32, and 36 if the study. The study collected data from these participants at 42 and 96 months after the first HPV or placebo dose. Children who became sexually active before their 3 dose of vaccine were excluded from the trial.

At follow-up visits, children were tested for these 4 strains of HPV. Researchers were looking for persistent disease, which means that an HPV infection was found in the same child, at 2 or more back to back visits that were at least 4 months apart, or in visits at least 12 visits apart (that did not have to be back to back) and that it was the same type of HPV that infected the child each time. Researchers also looked for disease in the children.

- In the EVG group, which included 256 females and 173 males, no cases of disease were found, and only 4 cases of persistent infection at or after 4 months were found (2 occurred in females and 2 occurred in males). None of these infections were still present after 12 months.
- In the CVG group 126 females were followed and 90 males. Among these youths, a total of 7 persistent cases were found (6 occurred in females and 1 occurred in a male). Four of the cases in females lasted at least 12 months or more. One of the female patients also suffered from disease (pre-cancer cells on the cervix) caused by the HPV infection.

Children from both the EVG and the CVG group had follow-up tests to check whether their immune system appeared to be activated against the strains of HPV in the vaccine. On average, this follow-up occurred at 5.2-6.8 years after the 3 vaccine doses for the EVG group and 3.5-4.7 years after the 3 vaccine doses for the CVG group. Researches found that blood levels indicated that the vaccine most likely worked through the 96-month follow-up for both boys and girls, but by then levels were somewhat lower compared to levels at the 7 month follow up.

The study found 1 serious adverse event follow vaccination that researchers thought was vaccine-related. The problem was cranial nerve paralysis that lasted for less than 3 weeks, was treated, and from which the patient fully recovered.

Authors concluded that the HPV4 vaccine works to protect against the 4 HPV strains for over 8 years. Significant serious safety issues were not seen for 8 years after vaccination in both genders. This information supports the recommendation to vaccinate all 11-12 year olds with HPV vaccine.