

HPV vaccination prevents genital warts in males

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(PhysOrg.com) -- A new international study shows the human papillomavirus (HPV) vaccine protects against genital warts and other lesions associated with HPV in males. HPV is the most common sexually transmitted disease and affects men and women. It has been linked to genital warts and cancers of the cervix and, more rarely, cancers of the vagina, anus, penis and mouth.

The <u>HPV vaccine</u> protects against four types of HPV infection: HPV-6, HPV-11, HPV-16, and HPV-18, and potentially also protects against <u>genital warts</u> or other lesions associated with these infections. Two HPV vaccines — Cervarix and Gardasil — are now recommended for girls aged nine and over to prevent cervical cancer.

Gardasil is also FDA-approved as a prevention of genital warts associated with HPV-6 and HPV-11, and in October 2010 was recommended for optional use in boys and young men from 9 to 26. The current study was carried out because until now the focus has been on using the <u>vaccine</u> to prevent <u>cervical cancer</u> and little research has been done on the effects of the vaccine in men.

The study included over 4,000 sexually active males aged 16 to 26 and originating from 18 countries and was a randomized double-blind and placebo-controlled clinical trial. There were two groups of subjects: one group was free of HPV at the start, and were given the vaccine; the other group were not all free of HPV at the start and were given either the vaccine or a placebo regardless of their HPV status.



The subjects were followed for the next two to three years and in the first group the efficacy against HPV-related lesions was over 90 percent. In the second group, of those given the vaccine only about 0.5 percent developed genital warts, while around 2.8 percent of those who received the placebo developed them. There was also a reduction in the incidence of HPV infections lasting for six months or more in those who were given the vaccine, but the difference was less dramatic.

Leaders of the study were Dr Anna Giuliano from the H. Lee Moffitt Cancer Center and Research Institute in Tampa, Florida, and Dr Joel Palefsky of the University of California, San Francisco. Dr Giuliano said Gardasil vaccine can prevent external infections, which means if boys are vaccinated early enough most cases of genital warts can be prevented. This raises the question of whether or not all boys and young men should be encouraged to be vaccinated. Dr Palefsky said the "burden of vaccination should not fall solely on girls and women" because men are affected by HPV as well as women. Men who have homosexual sex would not benefit from vaccination of girls and women.

Dr Palefsky said the vaccine appears to be safe, but the disadvantage is that a universal vaccination program of males would be costly, and most of the serious diseases caused by HPV, such as cervical <u>cancer</u>, affect only women.

The results of the study, published in the *New England Journal of Medicine* did not look at the effects of the vaccine on cancers. Merck, the manufacturer of Gardasil, designed and funded the research and analyzed the data, with the help of Drs Giuliano, Palefsky and colleagues. Additional funding was provided by the National Institutes of Health. Several members of the research team, including Dr Giuliano, also received speaking fees, travel cost reimbursements, or fees for board membership from Merck. Other members of the research team are employees of Merck and own Merck stock or options.



More information: Efficacy of Quadrivalent HPV Vaccine against HPV Infection and Disease in Males: *N Engl J Med* 2011; 364:401-411. <u>www.nejm.org/doi/full/10.1056/NEJMoa0909537</u>

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