



Even Closer? Update on HPV Vaccines

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Research published online in the April 7 issue of Lancet Oncology indicates Merck's HPV vaccine is highly effective at preventing both infection with HPV and associated diseases.

A phase II study was conducted with 552 women at sites in the U.S., Europe, and Brazil. Just over half of the subjects received Merck's Gardasil vaccine, which seeks to protect against the two HPV types most commonly found with cervical cancers (HPV 16 and 18) in addition to those most often detected with genital warts (HPV 6 and 11). Study participants were monitored with Pap smears, pelvic exams, and tests for HPV DNA and serum antibodies.

During three years of follow-up lead author Luisa Villa, Ph.D., and colleagues found only four women in the vaccine group contracted HPV and none actually developed disease such as cervical cancer, precancerous lesions (Cervical Intraepithelial Neoplasia, or CIN), or genital warts.

This is in contrast to subjects in the control group who received a placebo vaccine – 36 had HPV infection detected and 6 developed either CIN or genital warts (3 cases of each).

The authors conclude Gardasil shows great promise in reducing the incidence of HPV, cervical cancer, and genital warts, especially if larger phase III studies yield similar results. A great deal remains unknown about HPV vaccines, however, including if the duration of protection lasts longer than the 3-year period followed in this study.

GlaxoSmithKline (GSK) also has an HPV vaccine candidate, Cervarix, that phase II trials have shown to be effective at protecting women from HPV 16 and 18. GSK plans to file for European regulatory approval for its HPV vaccine in 2006 while Merck will seek FDA approval for Gardasil in late 2005.