

# New HPV approved after international phase 2/3 trial

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Approximately 12,000 women are diagnosed with cervical cancer each year in the United States and another 4,000 die annually from the disease. However, most cervical cancers are preventable through immunization against the human papillomavirus (HPV). A pivotal international phase 2/3 clinical trial involving Moffitt Cancer Center faculty demonstrated that vaccination with Gardasil 9 protects against nine HPV types, seven of which cause most cases of cervical, vulvar, and vaginal disease. The trial data indicate that if populations are vaccinated with Gardasil 9 approximately 90 percent of all cervical cancers worldwide can be prevented.

HPV is the most common sexually transmitted virus. The virus is typically cleared by a person's own immune system within two years, resulting in no lasting health concerns. However, in some cases, HPV can lead to significant health problems, including genital warts and cervical, vulvar, vaginal, penile, anal, and oropharyngeal cancers. There are no clinically approved tests to distinguish those who will clear the virus from those who are at high risk of developing cancer.

A large, randomized, international phase 2/3 trial was initiated to compare the safety and efficacy of Gardasil 9 with Gardasil in more than 14,200 women, ages 16 to 26. Gardasil 9 was 97 percent effective at preventing high-grade cervical, vulvar and vaginal [disease](#) caused by HPV 31, 33, 45, 52 and 58, and was equally effective at preventing disease induced by HPV 6, 11, 16 and 18. Each case of high-grade disease that occurred in patients vaccinated with Gardasil 9 occurred in

those who were already infected with HPV before they completed the study. This underlines "the importance of early vaccination prior to HPV exposure," said Giuliano. "More importantly, the vaccine was found to be safe with no significant vaccine-associated [health concerns](#)."

The vaccine trial [results](#) were published today in the *New England Journal of Medicine*, and the trial was funded by Merck & Co., Inc.

Until late 2014, there were two vaccines available to protect against as many as four HPV types - 6, 11, 16 and 18. The vaccines protect against 70 percent of HPVs that cause cervical cancer and also significantly reduce the risks of other types of cancer and genital warts. However, researchers have been trying to narrow the gap and completely eliminate any risk of HPV-induced disease. In December 2014, the Food and Drug Administration approved Gardasil 9, a vaccine that protects against nine HPV types (6, 11, 16, 18, 31, 33, 45, 52, and 58). According to Anna R. Giuliano, Ph.D., director of the Center for Infection Research in Cancer (CIRC) at Moffitt, Gardasil 9 "offers the potential to increase overall [cervical cancer](#) prevention from 70 to 90 percent, nearly eliminating this cancer from our communities."

**More information:** [medicalxpress.com/news/2015-02-...-cervical-cancer.html](http://medicalxpress.com/news/2015-02-...-cervical-cancer.html)

Provided by H. Lee Moffitt Cancer Center & Research Institute

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