Vaccine Protects Against Virus Linked to Half of All Cervical Cancers

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An experimental vaccine prevented women from becoming persistently infected with a virus that is associated with half of all cervical cancers, researchers reported in the November 21, 2002, issue of the New England Journal of Medicine (see the journal abstract of the study).

Human papilloma viruses (HPV) are extremely common sexually transmitted infections. In more than 90 percent of cases, the infections are harmless and go away without treatment.
However, certain types of HPV increase women's risk for cancer of the cervix (the neck of the womb). HPV-16, the virus type that was the focus of the current study, is found in 50 percent of cervical cancers. About a dozen other HPV types are involved in most other cases of the disease.

Rare instance

Although the vast majority of HPV infections do not progress to cervical cancer, the rare instance when HPV infection persists seems to be important to the development of the disease.
"If a woman tests positive for HPV once, that does not mean she is likely to get cervical cancer," says Allan Hildesheim, Ph.D., a senior investigator in the Division of Cancer Epidemiology and Genetics at the National Cancer Institute (NCI). "If she tests positive repeatedly over a period of years, that is more worrisome."
The current study, he says, "is an exciting first step toward a vaccine that can prevent cervical cancer." However, larger studies are needed to confirm that the vaccine is safe and effective for healthy young women, he adds.

Three shots

The study involved 2,392 women from 16 to 23 years in age. Participants were randomly assigned to receive three shots of either an HPV-16 vaccine or a placebo (a dummy substance). The study was double-blinded -- that is, neither the investigators nor the study participants knew who got the vaccine and who got the placebo. Participants were followed for an average of 17 months after

getting the third shot.
Some women had HPV-16 infections or other cervical abnormalities when they enrolled in the study; others developed the infection before they received all three shots. These women (859 enrollees) were excluded when the researchers calculated the vaccine's effectiveness.
Of the remaining 1,533 women, 41 developed HPV-16 infection -- all of these women were in the placebo group. Nine of the 41 women with HPV-16 infection went on to develop precancerous lesions (areas of abnormal tissue that may become cancerous). Twenty-two other women from the placebo group also developed precancerous lesions on their cervixes, but these were not associated with HPV-16.
By comparison, no one who got all three vaccine shots developed an HPV-16 infection. Twenty-two women receiving the vaccine did develop cervical abnormalities that can lead to cancer but these precancerous lesions were not associated with HPV-16.

Limitations

The vaccine tested in this study has several limitations, noted NCI's Hildesheim. For one thing, the vaccine offers no protection against other types of HPV that can also cause cervical cancer. In addition, it's unknown whether the vaccine's protection against HPV-16 is long-lasting. Finally, it does not prevent HPV-16 infections already present at the time of vaccination from progressing to cancer.
The study, which was supported by Merck Research Laboratories, will continue until all the participants have been followed for four years. Laura A. Koutsky, Ph.D., of the University of Washington in Seattle, led the team of researchers who conducted this study. An editorial by Christopher P. Crum, M.D., of Brigham and Women's Hospital in Boston accompanies the report.
There are other efforts to develop a cervical cancer vaccine, as well, including one trial sponsored by NCI that is not yet open to enrollment.

Pap Tests Still Needed

Most cervical cancers develop slowly through a series of abnormal changes in the cells of the cervix, changes most often related to an HPV virus. Regular Pap tests can detect these changes and the abnormal tissue can be removed. Pap tests would still be needed even if the experimental vaccine used in this study proves widely effective because the vaccine only works against one kind of HPV.
Pap tests are not 100 percent accurate, however, and many women do not have the tests regularly. In one national health survey, a fifth of women aged 18 to 64 had not had a Pap test in the past three years. A vaccine that prevented the HPV infections known to be behind most cervical cancers would be a powerful addition to disease prevention strategies.
Each year about 15,000 women in the United States learn that they have cervical cancer; an estimated 4,100 women will die of the disease this year. Worldwide, about 500,000 new cases of cervical cancer are diagnosed each year, resulting in 250,000 deaths. The disease is the second or third most common cancer among women (cervical cancer and colorectal cancer are virtually tied for second place after breast cancer).