

Vaccine holds promise in stopping CMV

- Each year, approximately 8,000 infants in the United States develop severe hearing, mental or movement impairments after becoming infected with cytomegalovirus (CMV), a common virus passed onto them while still in the womb. Now, published results of a trial involving 441 CMV-negative women give rise to optimism that a vaccine to prevent congenital CMV may be closer. Women who received the trial vaccine were 50 percent less likely to later become infected with CMV than were women who received a saline injection.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), sponsored the trial. The research team, led by pediatrician Robert Pass, M.D., of the University of Alabama at Birmingham, published their findings in the current issue of the *New England Journal of Medicine*.

"This trial demonstrates that a statistically significant degree of protection against maternal CMV can be achieved through vaccination," says Dr. Pass. "This is an important step along the path towards the ultimate goal - a vaccine that can protect infants from congenital CMV infection." He notes that a larger trial would be needed to conclusively prove the efficacy of any candidate CMV vaccine for this purpose. "However, for everyone interested in CMV vaccine development, this is an encouraging result." The trial evaluated an experimental vaccine made from a single CMV protein, glycoprotein B, which is known to provoke an immune response. The candidate vaccine, supplied by sanofi pasteur (Lyon, France), included an experimental adjuvant, MF59. An adjuvant is a substance added to a vaccine to improve the immune system response it elicits.

The clinical team invited healthy women between the ages of 14 and 40 who had given birth at the University of Alabama at Birmingham or at the University of Alabama College of Community Health Sciences in Tuscaloosa to participate in the trial. Of the 18,463 women they screened, approximately 24 percent were CMV-negative. This rate is consistent with figures from the Centers for Disease Control and Prevention, which estimates that between 50 and 80 percent of adults are infected with CMV by age 40.

After nearly seven years, the trial reached its enrollment goal. A total of 441 CMV-negative women, divided at random to receive the candidate vaccine or a saline injection, were evaluated. Vaccinations were given to women within one year after they had given birth. Most women received three doses of trial vaccine or saline injection; all received at least one dose. All the volunteers agreed to use birth control until two months after receiving the final injection.

In the final analysis, women who received the trial vaccine were significantly more likely to remain uninfected throughout the 42-month follow-up period than those who received the saline injection. Eight percent of vaccine recipients (18 of 225) eventually became infected with CMV, while 14 percent of saline injection recipients (31 out of 216) acquired a CMV infection by the end of the trial. There were no significant differences between the trial vaccine group and the saline injection group in frequency of fever, nausea, fatigue or rash. Most of the body-wide reactions were mild and lasted less than a day. Local reactions - such as pain, redness and swelling at the injection site - occurred more often in the vaccine group than in the group receiving saline injection. The majority of local reactions lasted less than a day.

Aspects of CMV biology have caused skeptics to question whether it is possible to prevent infection through vaccination, explains Dr. Pass. The virus is well adapted to persist in an infected person and is readily passed from person to person through direct contact with numerous bodily fluids: urine, saliva, breast milk, tears, blood, semen and vaginal fluid. Healthy people typically experience no symptoms after being infected with CMV. There is a strong immune response to the initial infection, but this immunity cannot always prevent subsequent infections if a person re-encounters the virus. Finally, natural infection does not elicit a response sufficient to completely eliminate the virus. On the contrary, once a person is infected, the virus persists for life.

About the Author

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