Concurrent FluMist, MMR, Varicella Vaccines OK

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SAN FRANCISCO — Physicians can administer the live attenuated influenza vaccine marketed as FluMist during the same healthy infant visit in which they administer the measles-mumps-rubella and varicella vaccines, without diminishing the safety or effectiveness of any of the vaccines, according to the results of a phase III trial reported at the annual meeting of the Pediatric Academic Societies.

The study randomized healthy infants at 44 sites in the United States during the months from May to October in 2001 and 2002. Infants also were randomized from November to May in 2001 and 2002 at three additional sites in Australia, where Dr. Nolan is the head of the school of population health at the University of Melbourne.

Investigators used the formulation of FluMist that is currently approved for healthy children and adults aged 5-49 years in the United States. MedImmune Vaccines Inc. of Gaithersburg, Md., manufacturer of FluMist, has announced that it will seek approval of a newer formulation in children as young as 6 months.

The principal change in the new product is that it can be refrigerated—the current formulation must be stored in a freezer—and delivered in a lower dose. MedImmune sponsored Dr. Nolan's trial.

Both FluMist formulations are delivered as an intranasal spray. This gives FluMist an advantage over the trivalent inactivated influenza vaccine (TIV) that is already approved for inoculation of healthy infants, according to Dr. Nolan.

"The vaccine [FluMist] is easier to give to babies because it is not an injection. They don't cry. They love it," he said. "And it appears to be as effective, if not more effective, than the injected vaccine. So it's a very promising vaccine for the future."

Dr. Nolan's study randomized infants into three groups:

► In Group 1, 411 infants received the measles-mumps-rubella (MMR II) and varicella (Varivax) vaccines and a placebo on the first visit. They were given FluMist on the second and third visits.

► In Group 2, 422 infants received MMR-II, Varivax, and FluMist on their first visit. They were given FluMist on the second visit, and a placebo on the third visit.

► In Group 3, the remaining 412 infants received FluMist alone during the first and second visits. They were given MMR II and Varivax on the third visit.

Investigators collected serum samples during office visits on days 0, 42, and 72 of the study. They reported that concurrent administration of FluMist with the other vaccines did not alter seroresponse rates or geometric mean titers to MMR II and Varivax vaccines. Similarly, there was no change in the strain-specific seroconversion rates or geometric mean titers for each of the three vaccine strains in the FluMist vaccine.

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A comparison of the first and second groups showed that children in Group 2 who were given concurrent vaccinations had significantly more rhinorrhea and nasal congestion during the following 42 days than did those in Group 1 (84% vs. 78%, respectively). Differences in other reactogenicity events were not statistically significant at 42 days.

During the 10 days after the first dose of FluMist, however, children in Group 2 who were given concomitant vaccinations had significantly more irritability (60% vs. 52%), fever over 101° F (29% vs. 14%), and vomiting (14% vs. 9%) than did children in Group 3 who received FluMist alone.

The most frequently reported adverse events after concurrent vaccination (Group 2) were diarrhea (17%) and otitis media (8%). Nine serious adverse events (including pneumonia, bronchiolitis, croup, viral chest infection and/or bronchospasm) may have been related to the study vaccine. The investigators concluded that concurrent administration was safe and well tolerated.

The meeting was sponsored by the American Pediatric Society, Society for Pediatric Research, Ambulatory Pediatric Association, and American Academy of Pediatrics. ■

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