RSV Immunization in Infants Is Safe and Provides High Antibody Levels

Nirsevimab monoclonal antibodies for infant imunization was safe and effective regardless of mother's RSV vaccination status.

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At a Glance

- Immunization against RSV is safe and effective in both infants and mothers, regardless of the mother's RSV vaccination status.
- Mother and infant pairs in the study experienced no adverse effects and demonstrated immunity against RSV regardless of when or how RSV immunization was delivered.
- Experts say the findings add to the large body of evidence showing RSV immunization efficacy, reassuring families who may need additional support.

Immunization against respiratory syncytial virus delivered to infants following birth is safe and provides high antibody levels, regardless of the mother's RSV vaccination status, according to new research presented at IDWeek 2025.

In the study, 181 mother/infant pairs from eight sites across the United States were divided into four groups with different methods and timing of RSV immunization: maternal vaccination with the RSVpreF vaccine for the mother while pregnant only; maternal vaccination and infant nirsevimab [monoclonal antibody] immunization immediately post-birth; maternal vaccination and infant immunization three months after birth; and infant immunization immediately post-birth only. Mothers and infants were assessed at birth and followed through four months of age.

Maternal vaccination and infant immunization alone and combined had no adverse effects on mothers or infants, according to the study's interim findings. Prior research had determined the safety of vaccination for mothers and babies but did not investigate the safety of immunization post-birth for babies whose mothers had received the vaccine while pregnant. The immunity of mothers and infants was measured by the level of RSV antibodies, and all four groups demonstrated high antibody levels at three months.

“Our research reassures new parents that all methods of immunization for RSV are safe and protective, which is especially important as the United States moves into its wave of seasonal respiratory illnesses,” said Christina A. Rostad, MD, director of the Emory Children’s Center Vaccine Research Clinic and presenting author. “The findings add to the large body of evidence that vaccines to prevent RSV are safe and effective.”

RSV is the most common cause of hospitalization in children under one year and is the leading cause of lower respiratory tract infections, which can lead to complications like bronchiolitis and pneumonia.

Vaccination against RSV is recommended by the Centers for Disease Control and Prevention for people between 32 and 36 weeks pregnant as well as immunization for all infants under eight months not otherwise protected through vaccination during pregnancy. While most infants do not need both products to provide protection through their first respiratory season, there are some clinical scenarios when infants may receive both. This study provides additional information on the safety and immunity provided by dual product administration.

This study is ongoing as researchers will follow up with participants to access immune durability for one year in mothers, infants and in breast milk. While the vaccine is proven to be safe and well tolerated in infants, researchers say durability of immunity for mothers and infants has yet to be fully described. The study is being conducted by the Infectious Diseases Clinical Research Consortium through funding from the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health (UM1AI48684).

In addition to Dr. Rostad, study co-authors include C. Mary Healy, MD, FIDSA; Jennifer Nayak, MD; Lalitha Parameswaran, MD, MPH; C. Buddy Creech, MD, MPH; Judith Martin, MD; Rebecca Brady, MD; Catherine Eppes, MD, MPH; Kimberly Jones-Beatty, DNP, CNM; Martina Badell, MD; Michael Quinn, MD, PhD; Mark Mulligan, MD; Anne-Marie Rick, MD, PhD; Katherine Sokolow, CPNP-PC/MSN; Braxton Forde, MD; Vasanthi Avadhanula, PhD; Pedro Piedra, MD; Kalyani Telu, MS; Pratap Kunwar, MS; Jinjian Mu, PhD; Fei Gao, PhD; Britta Flach, PhD; Marcela Pasetti, PhD; Christine Posavad, PhD; Joy Miedema, MPH; Cristina Cardemil, MD, MPH; James Campbell, MD, for the DMID 24-0003 PROMISE Study Group.

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