

Beyfortus study published in The Lancet Infectious Diseases shows benefit for infants beyond first RSV season

- First study showing that infants immunized against RSV in their first season had fewer RSV hospitalizations in their second season
- The study also showed a reduction of 85.9% in RSV-related lower respiratory tract infection hospitalizations in the first season

Data published in *The Lancet Infectious Diseases* and to be presented at RSVVW '26 conference in Rome

Paris, February 16, 2026. A universal respiratory syncytial virus (RSV) immunization program using Beyfortus (nirsevimab) was associated with a statistically significant reduction in RSV-related hospitalizations in the second RSV season among infants immunized during their first season, according to a new study published in *The Lancet Infectious Diseases*. The NIRSE-GAL study, conducted in Galicia, Spain, is the first prospective real-world population study to evaluate the impact of a universal Beyfortus immunization program during two consecutive RSV seasons. The study findings, comparing the number of hospitalizations in immunized infants during their second RSV season versus the number of expected hospitalization cases based on data from recent seasons, are being presented at RSVVW '26 (Respiratory Syncytial Virus Vaccines for the World) conference in Rome, Italy.

The coverage rate was 94.4% among the cohort (11,796 infants out of 12,492 eligible) and the study showed a substantial reduction of 85.9% (95% confidence interval [CI] 80.2–90.0) in RSV-related lower respiratory tract infection (LRTI) hospitalizations during the first season. The study also showed 55.3% (95% CI 22.5–74.3) fewer hospitalizations in the second RSV season among infants who received a dose of Beyfortus during infancy. By preventing severe RSV infections during the first months of life, a critical period of lung development, it is thought the infants may be less prone to subsequent admissions from either RSV or other infections.

"This universal RSV immunization program with Beyfortus showed decreased RSV-related hospitalizations and outpatient illness burden during the first season, with persistent impact seen on RSV hospitalizations through the second season," said **Federico Martínón-Torres**, Head of Pediatrics at Santiago University Hospital in Spain, and principal investigator of the NIRSE-GAL study. *"These results offer compelling population-based data to inform infant immunization strategies and economic evaluation models."*

"This study builds upon our wealth of evidence supporting the public health value of a Beyfortus immunization program," said **Thomas Triomphe**, Executive Vice President, Vaccines, Sanofi. *"It's exciting to see the significant impact of this infant immunization program during the first RSV season and truly remarkable to consider a benefit across two seasons."*

Further findings

The study also showed reductions in primary care consultations during the first RSV season, including:

- 30.8% (17.5–41.9) reduction in first consultations for acute bronchitis or bronchiolitis;
- 33.4% (21.6–43.4) reduction in consultations for lower respiratory tract infections and;
- 27.7% (14.9–38.5) reduction in consultations for wheezing or asthma.

Furthermore, rehospitalizations in infants previously hospitalized due to RSV decreased considerably during the second RSV season, with a 78.2% (25.6–93.6) reduction in RSV-related rehospitalizations and a 62.4% (30.9–79.6) reduction in LRTI rehospitalizations. These data

support the hypothesis that early protection against RSV-related damage to the lungs may have lasting beneficial effects on respiratory health.

About RSV

RSV is a highly contagious virus that can lead to serious respiratory illness for infants. It is a leading cause of hospitalization in all infants, with most hospitalizations for RSV occurring in otherwise healthy infants born at term. Older infants born before the RSV season are also at risk of RSV disease and make up around half of infant RSV hospitalizations. Two out of three infants are infected with RSV during their first year of life and almost all children are infected by their second birthday. Globally, in 2019, there were approximately 33 million cases of RSV-associated acute lower respiratory infections leading to more than three million hospitalizations and an estimated 26,300 in-hospital RSV-attributable deaths of children younger than five years. RSV-related direct medical costs, globally — including hospital, outpatient, and follow-up care — were estimated at c.€5 billion in 2017.

About Beyfortus

Beyfortus (nirsevimab) is the first RSV immunization designed to help protect all infants through their first RSV season, including for those born healthy at term or preterm, and those with health conditions that make them vulnerable to RSV disease. Beyfortus is also approved for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

With an extended half-life of 71 days, Beyfortus is a long-acting monoclonal antibody for the prevention of RSV lower respiratory tract disease in infants. Administration is timed to coincide with the RSV season and is provided directly to newborns and infants as a single dose. Beyfortus offers rapid protection without requiring activation of the immune system.

Along with efficacy and safety demonstrated in clinical studies, the effectiveness of Beyfortus has been evaluated in more than 50 real-world studies, including more than 400,000 infants who were immunized. Since the launch, over 11 million infants have been immunized with Beyfortus across more than 45 countries.

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