

Impact of universal nirsevimab prophylaxis in infants on hospital and primary care outcomes across 2 RSV seasons in Galicia, Spain (NIRSE-GAL): A population-based prospective observational study

Jan
2026

Authors: Razzini JL, Giné-Vázquez I, Jin J, Santiago-Pérez M-I, Pérez-Martínez O, Otero-Barrós M-T, Suárez-Gaiche N, Kramer R, Platero-Alonso L, Álvarez-Gil R-M, Ces-Ozores O-M, Nartallo-Penas V, Mirás-Carballal S, Piñeiro-Sotelo M, González-Pérez J-M, Rodríguez-Tenreiro-Sánchez C, Manzanares-Casteleiro A, Dacosta-Urbieta A, Álvarez-Smith C, Rivero-Calle I, Salas A, Durán-Parrondo C, Mallah N, Martínón-Torres F

Journal: *The Lancet Infectious Diseases*. 2026;S1473-3099(25)00742-X.



INTRODUCTION

RSV

Major cause of morbidity and mortality in children worldwide^{1,2}

Galicia, Spain

Introduction of nirsevimab as universal RSV prophylaxis in infants as part of the national immunization program

Young Infants

One-third of RSV-related LRTI hospital admissions and one-half of in-hospital deaths were among infants <6 months (2019)¹

NIRSE-GAL 2023-24 season

Reduction of RSV-related LRTI hospitalizations by a median of 89.2% in the overall cohort compared to prior RSV seasons³

KNOWLEDGE GAP Limited evidence on the impact of providing nirsevimab across multiple seasons



OBJECTIVE

- Assess medium-term impact of universal infant RSV prophylaxis with nirsevimab across inpatient and outpatient settings during two consecutive RSV seasons in Galicia



METHODS

STUDY INFORMATION



Study design

Population-based, prospective, observational study



Location

Galicia, Spain



Nirsevimab campaign date

September 25, 2023, to March 31, 2024



Population

12,492 eligible infants (n=11,796 immunized)*



Follow-up

Two consecutive RSV seasons (2023-24 and 2024-25), up to 18 months



Data

Data collection: October 2, 2023, to April 13, 2025 covering the first and second seasons
Data source: Galician Regional Surveillance Information System with linked hospital and primary care registries

*Among 11,796 immunized, 6019 were seasonal (infants born during the nirsevimab campaign) and 5777 were catch-up (infants younger than 6 months at the start of the campaign).



OUTCOMES

Primary Endpoint



RSV-related LRTI hospitalization

Exploratory Endpoints

- Deaths among RSV-related LRTI hospitalizations, LRTI hospitalizations, acute bronchitis or bronchiolitis hospitalizations, and all-cause hospitalizations

Secondary Endpoints

Hospitalization

First occurrence and first recurrence of:

- LRTI hospitalization
- Acute bronchitis/bronchiolitis hospitalization
- Pneumonia hospitalization
- All-cause hospitalization

Primary care outcomes

First and second visits for:

- Acute bronchitis/bronchiolitis
- Wheezing/asthma
- LRTI
- Respiratory infections
- Acute otitis media
- All otitis diagnosis



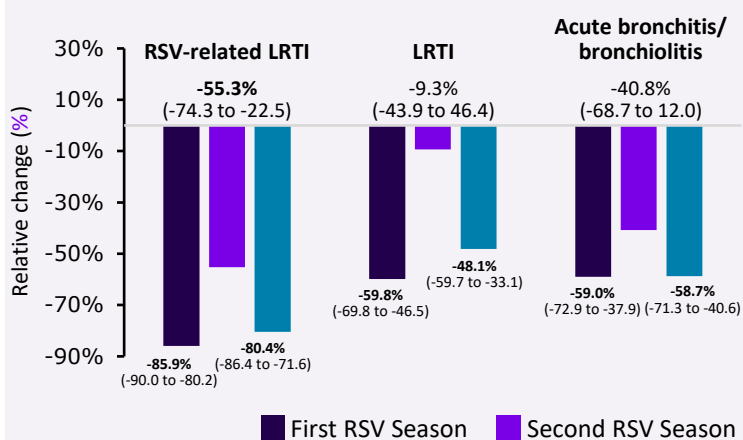


FIGURE 1. Relative change in incidence of first occurrences of hospitalization and primary care outcomes during the 1st and 2nd RSV seasons and up to 18 months follow-up vs historical cohorts

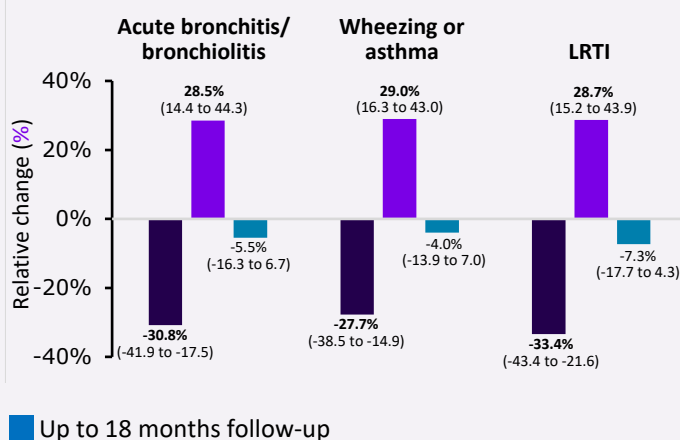
Only primary and selected secondary endpoints are shown



Hospitalization



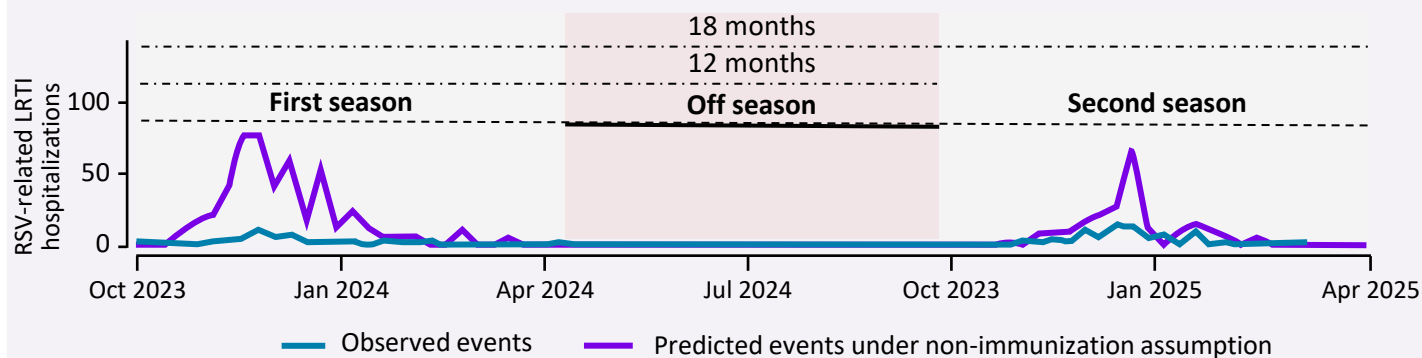
Primary Care Outcomes: First Visit



- The number needed to immunize in the first season to prevent one first-time hospitalization for RSV-related LRTI in the second season was **123**

- Second-season outpatient results are less consistent, with modest increases observed for some endpoints
- Several non-exclusive explanations merit consideration and further exploration:
 - Fluctuations in co-circulating pathogens
 - Diagnostic substitution as milder illnesses are managed increasingly in primary care
 - First visits for these endpoints were already prevented in the first season, making first-time primary care visits more likely to occur in the second

FIGURE 2. Weekly comparison between expected first RSV-related LRTI hospitalization under the no-immunization scenario and the observed hospitalization in 2023-24 cohort.



STRENGTHS

- Population-based design
- High nirsevimab coverage (94.4%)
- Linkage of hospital and primary-care records

LIMITATIONS

- Reliance on administrative codes
- Historical comparator design
- Low statistical power for uncommon endpoints



KEY MESSAGES

1

Universal infant nirsevimab prophylaxis markedly reduced RSV-related LRTI hospitalizations in the first season with sustained reductions into the second season

2

Moreover, the so-called lung-sparing effect of preventing severe RSV in the first months of life could be key

- By avoiding initial LRTI episodes, infants are less prone to subsequent admissions from either RSV or other infections, consistent with observed reductions in recurrent hospitalizations and wheezing

Glossary: IRR, incidence rate ratio; LRTI, lower respiratory tract infection.

Funding: The NIRSE-GAL study is funded by Sanofi and AstraZeneca through a research grant to the Healthcare Research Institute of Santiago and had no role in the study design, data collection, data interpretation, or writing of the report.

References: 1. Li Y, et al. *Lancet* 2022;399(10340):2047–2064. 2. Wildenbeest JG, et al. *Lancet Respir Med* 2023;11(4):341–353. 3. Mallah N, et al. *Lancet Infect Dis.* 2025;25(2):e62–63.

For use by Sanofi Medical Affairs for scientific exchange and medical discussions only. Do not photograph, copy or distribute.

©2026 Sanofi. All rights reserved.

