PUBLICATION CARD

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

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INTRODUCTION

RSV | Major cause of morbidity and mortality in children worldwide[1,2]

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

Galicia, Spain | Introduction of nirsevimab as universal RSV prophylaxis in infants as part of the national immunization program

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 seasons[3]

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

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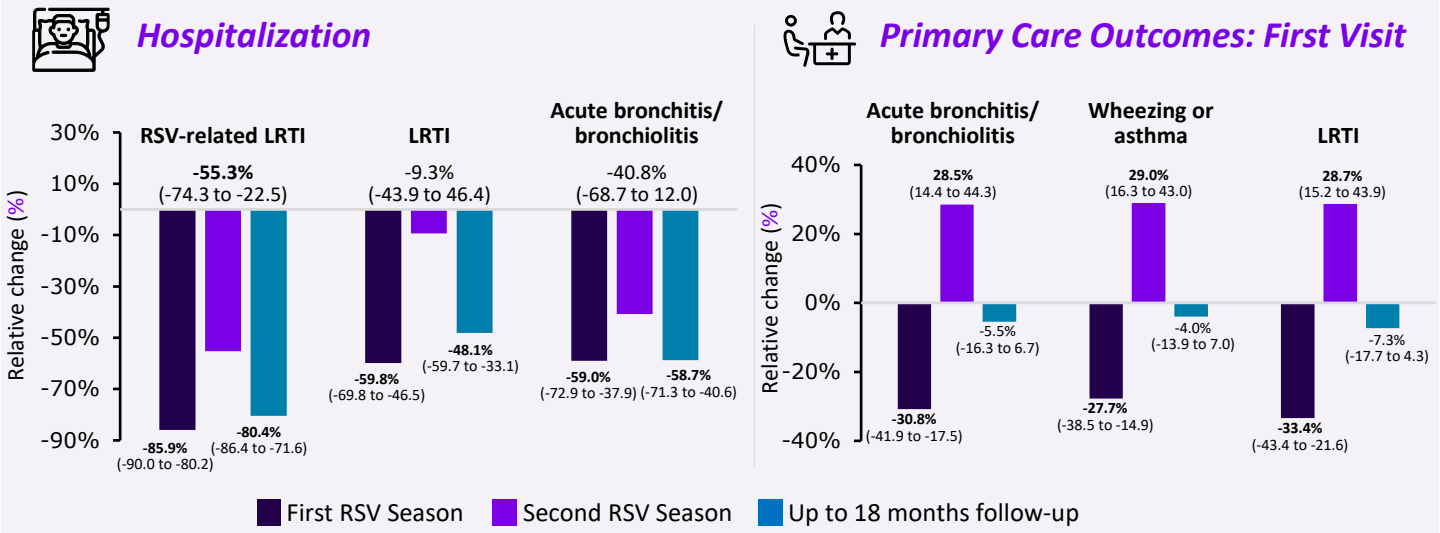
RESULTS

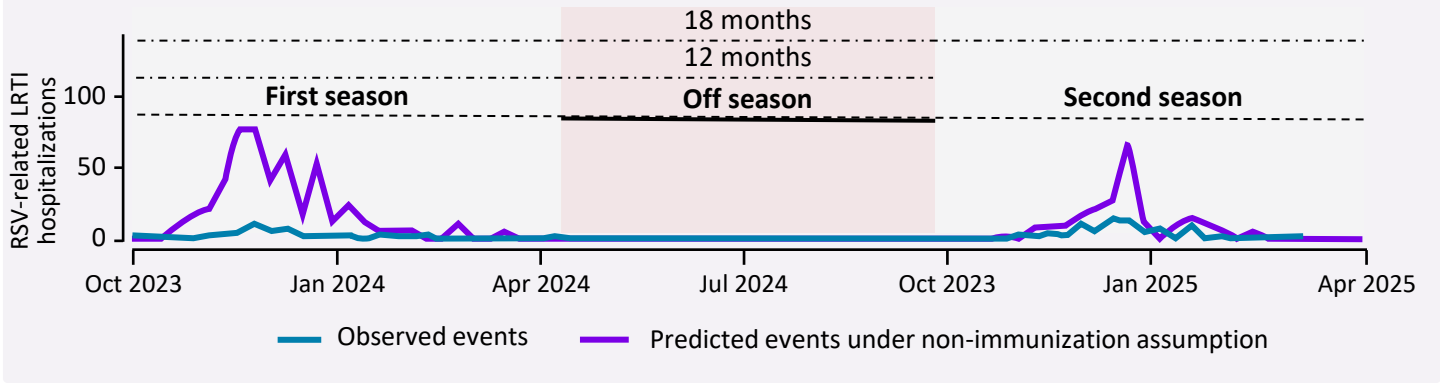
FIGURE 1. Relative change in incidence of first occurrences of hospitalization and primary care outcomes during the 1st and 2nd RSV seasons and up to 18 months follow-up vs historical cohorts
Only primary and selected secondary endpoints are shown



- 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.

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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.

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