

Nirsevimab vs RSVpreF vaccine for respiratory syncytial virus–related hospitalization in newborns

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INTRODUCTION



Immunization options

Nirsevimab and maternal vaccination with RSVpreF at 24–36 weeks gestation were approved for use in France in 2022 and 2023, respectively^{1,2}



French experience

Prior population-based study of nirsevimab showed reductions of 65% in RSV-associated LRTI hospitalizations and 75% in PICU admissions³

KNOWLEDGE GAP Considering differences in immunologic mechanisms and timing of administration, no direct comparison (to date) has evaluated infant nirsevimab and maternal RSVpreF vaccination for preventing severe RSV outcomes in early infancy



OBJECTIVE

- Compare the associations of infant nirsevimab immunization vs maternal RSV vaccination for preventing RSV-related hospitalization in infants in France



METHODS

STUDY INFORMATION



Study design

Population-based, retrospective cohort study



Location

France



RSV immunization campaign dates

Sept 1, 2024, to Jan 31, 2025



Data

Data collection: Oct 1, 2024, to Feb 28, 2025
Data source: French National Health Data System nationwide database



Follow-up

Discharge from birth hospitalization until outcome event, unrelated death, or February 28, 2025 (whichever occurred first)



OUTCOMES

Primary outcome



RSV-associated LRTI hospitalization identified using ICD-10 RSV codes (laboratory confirmed)

Secondary outcomes

- RSV-associated LRTI requiring admission to a PICU or high dependency unit, ventilator support, or supplemental oxygen
- Length of inpatient hospitalization
- Extracorporeal membrane oxygenation use
- Nitric oxide use
- In-hospital death



POPULATION

107,778

- Infants born Sept 1 to Dec 31, 2024
- Discharged from maternity wards on or after Oct 1, 2024
- Immunized via **nirsevimab** during their birth stay or born to mothers who received **RSVpreF vaccine**

85,476

Eligible to be included

Nirsevimab

62,340

RSVpreF vaccine

23,136

1:1 matching for discharge day, sex, region of residence, and gestational age

Match rate 92%

Nirsevimab

21,280

RSVpreF vaccine

21,280





RESULTS



After propensity score matching, **maternal and infant characteristics were balanced** between the 2 groups



52%
male



99%
born at term

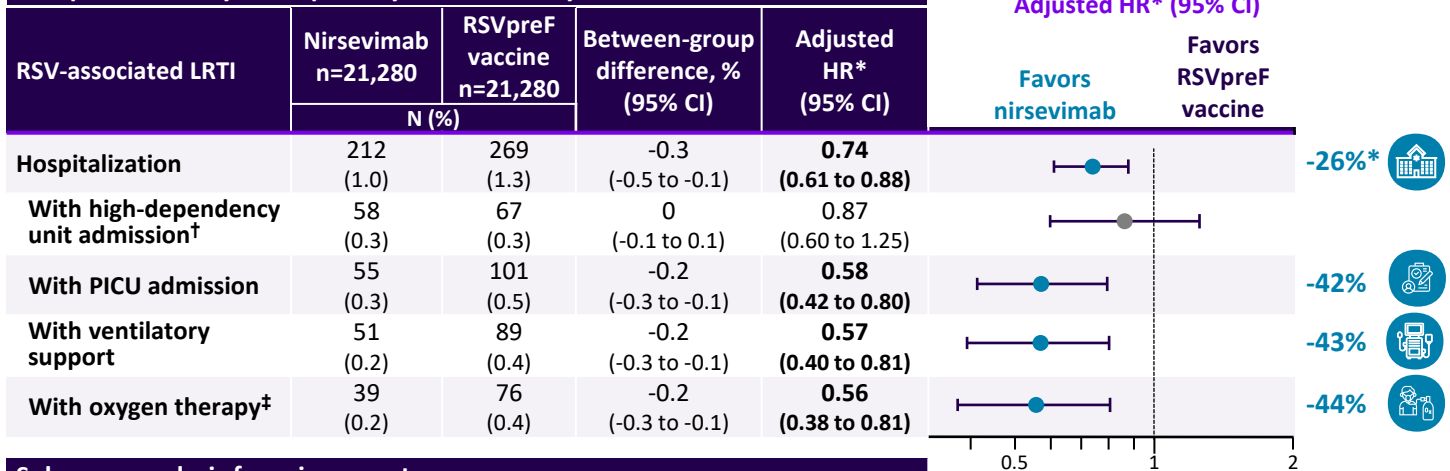


3.7-3.8 days
mean age at discharge

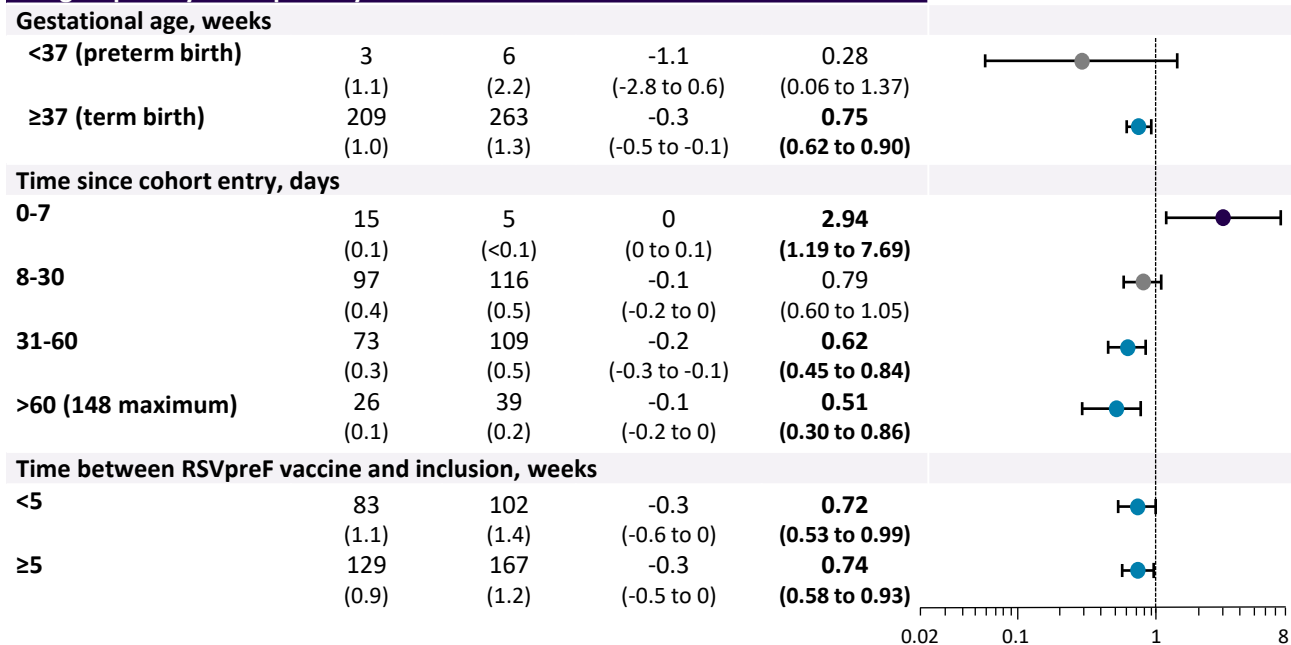


91%
born in Nov or Dec

Comparative analysis for primary and secondary outcomes



Subgroup analysis for primary outcome



*Derived using an inverse probability of treatment weighting method that was applied to the matched dataset to further balance the residual covariates.
†Defined as a unit providing continuous monitoring and specialized care for infants requiring a higher level of observation and treatment than standard pediatric wards but not an intensive care unit. ‡Includes the administration of supplemental oxygen but does not include ventilator or respiratory support.

STRENGTHS

- Large sample size
- Longitudinal, comprehensive data on the entire French population with maternal and infant characteristics
- Alignment with eligibility timing, treatment allocation, and start of follow-up within the same RSV epidemic period and population
- Extensive adjustment for potential confounders
- Bias minimization, including temporal biases
- Validated coding of diagnoses and procedures, limiting misclassification and missing data

LIMITATIONS

- Under-represented children born early in the RSV season
- Limited follow-up to a single RSV season
- No RSV subtype analysis
- Longer-term differences and safety not assessed
- Unmeasured confounding—including parents' healthcare-seeking behavior, household smoking, and daycare attendance—could not be excluded



KEY MESSAGES

1

Passive infant immunization with nirsevimab was associated with lower risks of infant RSV-related hospitalization and severe outcomes vs maternal RSVpreF vaccination

2

This data compares different strategies for RSV prevention and may be of interest for policy makers when considering recommendations

Glossary: CI, confidence interval; HR, hazard ratio; ICD-10, International Classification of Diseases, Tenth Revision; LRTI, lower respiratory tract infection; PICU, pediatric intensive care unit; RSVpreF, RSV prefusion F protein.

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