Gac Sanit. 2026;40(S4):62

Gaceta Sanitaria

https://www.gacetasanitaria.org

414 - COMPARATIVE IMPACT OF NIRSEVIMAB ON RSV HOSPITALISATIONS IN NEWBORNS IN SPAIN AND PORTUGAL, 2024-2025 SEASON

A.V. Vilhena, S.C. Campos, A.R. Rodrigues, V.G. Gaio, D.A. Aguilar, M.L. Lozano, S.M. Monge, A.M. Machado, Group SiVIRA

UA; INSA; UNED; ENS-ISCIII; ENSP; Hospital San Eloy; CNE-ISCIII; CIBERINFEC.

Resumen

Background/Objectives: Respiratory syncytial virus (RSV) is a leading cause of severe respiratory disease in young infants and a major global healthcare burden. Nirsevimab, a novel RSV-targeting monoclonal antibody, was implemented as routine infant immunisation in Spain in the 2023-2024 RSV season and in Portugal in 2024-2025. We estimated the impact of this strategy on RSV-related hospitalisations among eligible newborns during the 2024-2025 RSV season in both countries.

Methods: We conducted an ecological study using national birth statistics to identify the most comparable infant cohorts targeted for immunisation in each country (Spain: October-March; Portugal: August-March). The number of RSV-related hospitalisations between October 2024 and March 2025 in Spain was estimated by extrapolating the equivalent rates from Spain’s severe acute respiratory infections surveillance system to the study population. In Portugal, we extracted primary RSV diagnoses using International Classification of Diseases version 10th codes from the national hospital discharge database. By integrating these data with country-specific immunisation coverage (Spain: > 90%; Portugal: 86%) and country-specific Nirsevimab effectiveness (Spain: 70.4%; Portugal: 79.1%), we derived the Number of Averted Events (NAE), NAE rates per 100,000 infants, Prevented Fraction (PF), and Number Needed to Immunise (NNI). Monte Carlo simulations were used to derive 95% confidence intervals (95%CI).

Results: In Spain, Nirsevimab was estimated to avert 2,112 RSV-related hospitalisations (95%CI: 728-4,318), corresponding to an NAE rate of 1,331 per

0213-9111 © 2026 SESPAS. Publicado por Elsevier España, S.L.U. Todos los derechos reservados

100,000 eligible infants (95%CI: 459-2,720), a PF of 68% (95%CI: 42-81) and an NNI of 72 (95%CI: 35-208). In Portugal, the NAE was 663 (95%CI: 316-1,053), corresponding to an NAE rate of 1,164 per 100,000 eligible infants (95%CI: 554-1,850), a PF of 68% (95%CI: 51-77), and an NNI of 74 (95%CI: 47-156).

Conclusions/Recommendations: This Iberian analysis confirms that Nirsevimab substantially reduced RSV-related hospitalisations in eligible newborns during the 2024-2025 season in both countries, preventing 68% of cases and achieving low NNI (Spain: 72; Portugal: 74) despite differences in coverage, effectiveness, and implementation timing. The convergence of impact indicators highlights the programme’s resilience and underscores the importance of achieving and maintaining high coverage to sustain high infant-level impact.

0213-9111 © 2026 SESPAS. Publicado por Elsevier España, S.L.U. Todos los derechos reservados