

บทความพิเศษ

Nirsevimab กับบทบาทในการป้องกันการติดเชื้อ RSV ในทารกและเด็กเล็ก

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บทคัดย่อ

การติดเชื้ออาร์เอสวี (Respiratory Syncytial Virus; RSV) เป็นปัญหาสำคัญด้านสาธารณสุขทั่วโลก โดยเฉพาะในทารก ซึ่งทำให้อัตราการเข้ารับการรักษาในโรงพยาบาลสูงทั้งจากภาวะหลอดลมฝอยอักเสบและภาวะปอดอักเสบ แม้ว่าตัวโรคจะส่งผลกระทบต่อสุขภาพอย่างรุนแรง และเด็กส่วนใหญ่มักจะเกิดการติดเชื้อ RSV ภายในอายุ 2 ปี ซึ่งในปัจจุบัน วัคซีนป้องกันการติดเชื้อ RSV ยังจำกัดอยู่ที่การให้วัคซีนแก่หญิงตั้งครรภ์ ขณะที่แนวทางการป้องกันการติดเชื้อ RSV รูปแบบอื่นในทารกยังมีข้อจำกัดในทางปฏิบัติ บทความนี้จึงนำเสนอผลกระทบของการติดเชื้อ RSV ทั้งในระดับโลกและในประเทศไทย ความท้าทายในการพัฒนาวัคซีนสำหรับการติดเชื้อ RSV และชี้ให้เห็นบทบาทของ monoclonal antibody ในฐานะทางเลือกในการป้องกันโรคเพิ่มเติมให้แก่ทารก บทความนี้จะมุ่งเน้นที่ nirsevimab ซึ่งเป็น monoclonal antibody รุ่นที่สอง ที่สามารถให้การป้องกันได้ครอบคลุมตลอดฤดูกาลจากการให้เพียงหนึ่งครั้ง ซึ่งสามารถแก้ไขข้อจำกัดของวิธีการป้องกันแบบเดิม โดยได้กล่าวถึงข้อมูลด้านประสิทธิภาพ ความปลอดภัย สถานะการขึ้นทะเบียน และการบูรณาการเข้าสู่ระบบสาธารณสุข

คำสำคัญ: Respiratory Syncytial Virus (RSV), Nirsevimab, Monoclonal antibodies, RSV prevention

The role of nirsevimab in RSV prevention among infants and young children

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Abstract

Respiratory syncytial virus (RSV) significantly impacts global public health challenges, especially among infants, leading to high hospitalization rates due to bronchiolitis and pneumonia. Despite the substantial disease burden and nearly universal infection by age two, RSV prevention strategies continue to evolve, including maternal immunization and infant immunoprophylaxis. This review examines the global and Thai-specific impacts of RSV, discusses challenges in vaccine development, and reviews monoclonal antibodies as an approach to RSV prevention. Nirsevimab, a second-generation monoclonal antibody administered as a single dose for infant immunoprophylaxis, is discussed in the context of current RSV prevention. The review summarizes available evidence on the efficacy, safety, regulatory status, and potential integration of nirsevimab into RSV prevention strategies.

Keywords: Respiratory Syncytial Virus (RSV), Nirsevimab, Monoclonal antibodies, RSV prevention

Introduction

RSV: A Common Respiratory Threat

Respiratory syncytial virus (RSV) is a single-stranded RNA virus in the Paramyxoviridae family. It is responsible for a significant health burden across various age groups due to its capacity to cause severe respiratory illnesses. The virus produces essential proteins, including the F (fusion) and G (attachment glycoprotein) proteins, which are crucial for its ability to infect host cells and spread. RSV is classified into two main subtypes, A and B, both of which circulate during seasonal outbreaks within the same period.¹

The clinical manifestations of RSV infection vary by age group. In infants, RSV typically begins with mild symptoms such as nasal congestion and sneezing. However, it can rapidly progress to severe respiratory distress, characterized by coughing, wheezing, and the use of accessory muscles for breathing. Severe cases may involve lethargy and apnea, particularly in premature infants who are more vulnerable due to their immature respiratory systems.¹ In elderly individuals and people with significant underlying medical conditions, RSV infection is associated with a higher risk of severe illness and may lead to fatal outcomes.²

Diagnosis of RSV bronchiolitis in infants is primarily clinical, based on the observation of characteristic symptoms and findings from the physical examination. Imaging and laboratory tests are typically used to rule out other conditions rather than to confirm RSV, as these are not routinely required. However, infants and children who are admitted to pediatric intensive care unit for pneumonia usually require definite diagnosis of RSV to tailor their management.^{1,3}

Treatment for RSV is primarily supportive, focusing on managing symptoms. This includes providing oxygen therapy and ensuring adequate nutrition and hydration.² Conventional treatments such as bronchodilators and corticosteroids are not effective and are not routinely recommended.¹ Currently, no highly effective antiviral agents are available for treating RSV infection. Ribavirin, an antiviral medication, is occasionally used in specific high-risk cases; however, its effectiveness remains controversial, and its use is restricted due to potential side effects and high cost.⁴

Several antiviral agents are being evaluated in clinical trials as potential treatments for RSV infection, reflecting the ongoing need for effective therapies, particularly for children at risk of severe disease. Among the investigational agents, ziresovir has progressed furthest in clinical development, with Phase III efficacy data now available. Regulatory submission for ziresovir was being pursued in China, with plans for future

expansion to other countries. However, these agents remain investigational and are not currently available for routine treatment of RSV infection.⁵

Despite advancements in supportive care, the lack of a universal RSV vaccine places many infants at risk of severe infections each year, highlighting a significant unmet medical need. Current preventive strategies for RSV are limited, as no pediatric RSV vaccines are available. The bivalent RSV prefusion F protein (RSVpreF) vaccine can be used for maternal immunization to facilitate passive antibody transfer, providing protection for infants during their first six months of life.^{2,6} The vaccine development efforts have faced significant challenges due to the virus's complex immunogenicity profile and genetic variability. These characteristics make it difficult to produce a vaccine that is both safe and effective across different populations.⁷

This article is based on a summary report focusing specifically on nirsevimab and its role in RSV prevention in infants. While other RSV prevention options, including clesrovimab and the bivalent RSV prefusion F protein (RSVpreF) vaccine, are also available in Thailand, the primary focus of this article is nirsevimab. These other prevention strategies are acknowledged where relevant to provide appropriate context and comparison.

Epidemiology of RSV

The burden of RSV across all infants is immense, with almost universal infection by two years of age. Annually, RSV contributes approximately to 33 million cases of acute lower respiratory infections worldwide, leading to approximately three million hospitalizations and significant mortality among infants. The impact of RSV is particularly acute in low- and middle-income countries, where over 95% of RSV-associated lower respiratory tract infection (LRTI) episodes occur, highlighting significant disparities in healthcare access and outcomes.⁸

In Thailand, surveillance data from 2025 documented 46,999 cumulative cases, corresponding to an overall incidence rate of 72.40 per 100,000 population. Children aged 0–4 years experienced the highest disease burden, with 37,968 cases and an incidence of 1,332.20 per 100,000 population, followed by children aged 5–9 years with 3,914 cases (110.00 per 100,000 population). Overall, 18,248 cases (38.83%) required inpatient care, while 28,751 (61.17%) were managed in outpatient settings. Seven deaths were reported, occurring primarily among children younger than 5 years and older adults.⁹

RSV infection in Thailand shows a distinct seasonal pattern, with activity typically increasing during the rainy season and peaking between July and November.¹⁰ Recent surveillance has also demonstrated year-to-year variation in the predominance of RSV subgroups. RSV-B predominated in 2023 and 2025, whereas RSV-A was more prevalent in 2024. Both subgroups circulate among young children.¹¹

RSV in infants

High hospitalization rates and the need for intensive care in infants during seasonal RSV peaks place substantial strain on healthcare resources. Severe RSV infection may also be associated with longer-term respiratory sequelae, including recurrent wheezing, asthma, persistent cough, and impaired lung function.¹² Together, these acute and chronic impacts highlight the urgent need for early intervention, preventive strategies such as vaccination, and timely treatment to reduce both immediate and long-term consequences in vulnerable children.

The Evolution of RSV prevention in infants

The development of a vaccine for RSV has been marked by significant challenges and setbacks since the 1960s. Initial efforts focused on creating a formalin-inactivated RSV vaccine, but these trials were halted after the vaccine led to enhanced respiratory disease (ERD) in infants upon subsequent natural RSV infection, causing severe lung inflammation and increasing hospitalization rates. This early failure underscored the complexity of RSV's immunogenicity profile and led to a pause in vaccine development for decades.⁷

Renewed efforts in the 1990s shifted focus toward passive immunization with monoclonal antibodies. Palivizumab emerged as the first monoclonal antibody that targets RSV fusion protein, thereby inhibiting viral entry into host cells.¹³

Although palivizumab reduces RSV-related hospitalizations by approximately 39 to 60 percent in high-risk infants including those born prematurely, with chronic lung disease, or with significant congenital heart disease, its overall clinical impact remains limited. High production costs and the requirement for monthly administration throughout the RSV season significantly constrain its feasibility, scalability, and cost-effectiveness for widespread use.^{14,15}

Long-acting agents such as nirsevimab provide season-long protection with a single dose, addressing key limitations of palivizumab by reducing dosing frequency while maintaining broad efficacy.¹⁵⁻¹⁷ These antibodies confer immediate immunity, which is critical for protecting infants during their first RSV season and serve as an interim strategy while effective vaccines for universal use continue to be developed.

Advances in active immunization have also led to the development of maternal RSV vaccination. WHO SAGE recommended maternal RSV vaccination in December 2024, providing an additional strategy to protect infants through transplacental transfer of maternal antibodies while avoiding the risk of vaccine-enhanced disease (VED) associated with earlier RSV vaccine approaches.¹⁸

More recently, clesrovimab, another long-acting monoclonal antibody, was approved by the US FDA in June 2025 for administration in neonates and infants during their first RSV season, followed by a recommendation from the US Advisory Committee on Immunization Practices for RSV prevention in infants under 8 months of age.^{15,16}

In the ongoing battle against RSV, second-generation monoclonal antibodies, including nirsevimab, have expanded the available options for RSV prevention. Unlike palivizumab, which require monthly administration, nirsevimab provides extended protection with a single-dose injection, offering a more convenient approach to RSV prevention.¹⁹ This advance may facilitate broader and more practical implementation of RSV prophylaxis.

Nirsevimab: Evidence and considerations for RSV prevention

In Thailand, a middle-income country facing multiple competing infectious disease priorities, efficient healthcare resource allocation remains challenging. This complexity complicates the implementation of widespread RSV immunization programs, despite their potential to substantially reduce disease burden. Nevertheless, preventive options such as nirsevimab¹⁶ are becoming increasingly accessible. Approved by the Thai Food and Drug Administration (FDA) in June 2024,²⁰ nirsevimab has already been widely adopted in Europe and the United States.

Nirsevimab targets a highly conserved epitope at antigenic site Ø on the prefusion conformation of the RSV fusion (F) protein, a key structure involved in viral entry into host cells, thereby neutralizing the virus and preventing membrane fusion. Unlike its predecessor, palivizumab, nirsevimab is designed with an enhanced half-life due to a triple amino acid substitution (YTE) in the Fc region. This modification increases its binding affinity to the neonatal Fc receptor (FcRn), facilitating recycling and reducing lysosomal degradation, thereby extending its duration of action in the bloodstream.^{21,22} Nirsevimab has an extended half-life of 68.7 days, as demonstrated in the MELODY study.²¹⁻²³

Nirsevimab's mechanism of action involves blocking viral entry into host cells, effectively neutralizing the virus and preventing infection. The composition allows it to remain effective against a wide range of RSV variants, maintaining neutralizing activity against over 99% of RSV strains observed in clinical studies. This broad-spectrum efficacy is critical in addressing the genetic diversity of RSV and ensuring consistent protection.²⁴

Nirsevimab has demonstrated robust efficacy and safety across Phase IIb and Phase III clinical trials. In a Phase IIb study, nirsevimab reduced RSV-associated lower respiratory tract infections by 70.1% in preterm infants.^{25,26} In the Phase III MELODY trial, it reduced medically attended RSV lower respiratory tract infections by 74.5% (95% CI, 49.6 to 87.1; $p < 0.001$) in late preterm and term infants.²⁵

Real-world evidence has subsequently supported these clinical trial findings. A 2025 systematic review and meta-analysis found that nirsevimab was associated with reduced RSV-related hospitalization and intensive care unit admission in infants aged ≤ 12 months.²⁷ In a multicenter US study, nirsevimab was estimated to be 80% effective against RSV-associated ICU admission and 83% effective against acute respiratory failure in infants.²⁸

Across trials, adverse event rates were comparable to placebo, with no significant increase in serious adverse reactions, including hypersensitivity, thrombocytopenia, or immune complex disease.^{21,26} Recent real-world studies have similarly reported a favorable safety profile, with no new safety concerns identified.²⁹ These findings further support the favorable benefit-risk profile of nirsevimab and its effectiveness in reducing severe RSV disease in routine clinical settings.

A summary of clinical trial results is presented in Table 1, providing key insights into nirsevimab's efficacy and safety across diverse populations.

Table 1 Summary of nirsevimab clinical trials, efficacy, and safety results^{21,22,25,26}

Study phase	Clinical trial name	Population	Efficacy (%reduction)	Key safety observations	Notes
Phase IIb	NURSERY preterm trial	Preterm infants (<35 weeks GA)	70.1% reduction in RSV-associated LRTI	Comparable adverse events to placebo, no severe hypersensitivity reactions	Population included infants at high risk of severe RSV disease, tested across multiple countries.
Phase III	MELODY	Late preterm and term infants	74.5% reduction in medically attended RSV-LRTI (95% CI, 49.6–87.1; p<0.001)	Adverse event rates consistent with placebo	Focused on healthy infants entering their first RSV season, demonstrating broad applicability.
Phase IIIb	HARMONIE	All infants, including those with comorbidities	Data pending long-term follow-up assessments	Preliminary safety results align with prior trials	Study designed to capture diverse populations and real-world settings for broader applicability.

Comparing with the first generation, nirsevimab has an extended half-life that enables season-long protection with a single injection. This reduces the frequency of administration and may reduce the complexity, logistical burden, and costs associated with repeated dosing, while improving adherence and access to RSV prophylaxis for a broader infant population.³⁰ Unlike palivizumab, which has been limited to high-risk infants, nirsevimab supports a more inclusive prevention strategy and may simplify RSV management.³¹ In parallel, maternal RSV vaccination offers an alternative approach through transplacental antibody transfer. RSVpreF vaccine, approved in the United States and European Union in 2023, is administered during late pregnancy and provides peak protection in the first three months of life.³² Compared with monoclonal antibodies, maternal RSV vaccination can be readily integrated into routine antenatal care,

potentially enhancing cost-effectiveness and accessibility. However, uptake remains variable, influenced by provider confidence, perceptions of vaccine safety, and public awareness. Maternal RSV vaccination provides infant protection through transplacental transfer of maternal antibodies, while nirsevimab provides direct passive immunization after birth through a single dose. Both approaches can provide protection during early infancy, with their use depending on factors such as vaccination timing, infant age, and access.³²

Nirsevimab in clinical practice

As of 2025, nirsevimab, a monoclonal antibody targeting respiratory syncytial virus, has received regulatory approval in multiple regions, including the United States, the European Union, and more recently Thailand.³³ These approvals underscore its emerging role in RSV prophylaxis, offering a single-dose alternative to the repeated dosing required with the first generation monoclonal antibodies.

Nirsevimab is indicated for the prevention of RSV in infants during their first RSV season, particularly targeting those who are at high risk for severe disease, including premature infants and those with congenital heart conditions.^{16,22} Its use is recommended to reduce RSV-related hospitalizations and healthcare visits in this vulnerable population. Nirsevimab is indicated for the prevention of RSV lower respiratory tract disease in infants according to age, season, and risk factors specified in the applicable regulatory and clinical recommendations.

Leading public health authorities, including the Advisory Committee on Immunization Practices (ACIP), the Centers for Disease Control and Prevention (CDC), and the European Medicines Agency (EMA), recommend RSV prevention through either maternal RSV vaccination or infant long-acting monoclonal antibody administration, but not both for most infants.

- United States (ACIP/CDC Recommendations)^{32,34,35}
 - Maternal RSV vaccination: ACIP and CDC recommend that pregnant individuals receive a single dose of the maternal RSVpreF vaccine at 32–36 weeks' gestation, ideally administered between September and January in most of the continental United States, to provide passive immunity to the infant.
 - Infant monoclonal antibodies: Alternatively, a long-acting monoclonal antibody is recommended for all infants younger than 8 months who are born during or entering their first RSV season. High-risk infants (aged 8–19 months) entering their second RSV season are also eligible.

- Co-administration consideration: Infants born less than 14 days after maternal RSV vaccination should still receive nirsevimab, as their passive immunity may not be sufficient.
- European Union (EMA Recommendations)^{21,36}
 - The EMA has approved a long-acting monoclonal antibody such as nirsevimab for the prevention of RSV lower respiratory tract disease in neonates and infants during their first RSV season. It is administered as a single intramuscular injection either before the RSV season or at birth for infants born during the RSV season.
- Thailand
 - Recommendation for the use of a long-acting monoclonal antibody, nirsevimab, by the Royal College of Pediatricians of Thailand³⁷

First RSV season:

- Recommended for infants when maternal RSV vaccination was not administered, vaccination history is unknown, or birth occurs within 14 days of maternal RSV vaccination.
- Indicated for all healthy infants < 8 months of age and for infants <12 months at high risk of severe RSV disease, including chronic lung disease of prematurity requiring recent therapy, severe immunodeficiency, severe cystic fibrosis, and hemodynamically significant congenital heart disease; use may be considered in healthy infants aged 8–12 months.

Second RSV season:

- Nirsevimab is recommended for children <19 months with risk factors for severe RSV disease and may be considered for those aged 19–24 months with persistent risk factors.

These recommendations are supported by clinical evidence demonstrating the effectiveness of both strategies in preventing RSV-associated lower respiratory tract infection in infants. Maternal RSV vaccination provides early passive immunity from birth, whereas nirsevimab offers direct, long-lasting antibody protection throughout the RSV season. Recent real-world evidence from France has provided a direct comparison of these approaches. In a nationwide population-based cohort study conducted during the 2024–2025 RSV season, nirsevimab was associated with a lower risk of RSV-related hospitalization in newborns compared

with maternal RSVpreF vaccination, as well as lower risks of severe outcomes including intensive care admission, ventilatory support, and oxygen therapy.³⁸ However, as an observational study, these findings should be interpreted in the context of potential residual confounding and do not establish superiority of one strategy in all settings.

The choice between maternal RSV vaccination and infant nirsevimab should therefore consider maternal vaccination status and timing, infant age and risk factors, RSV seasonality, local recommendations, and access to prevention strategies.^{34,38} Both approaches provide important opportunities to reduce the burden of RSV disease in infants, while nirsevimab offers an alternative when maternal vaccination was not administered or when additional protection is recommended according to local guidance.

Conclusion

Expert perspectives on RSV prevention in Thailand

A long-term monoclonal antibody such as nirsevimab is an important addition to the available strategies for RSV prevention in infants, with clinical trial and emerging real-world evidence supporting its efficacy in reducing RSV-associated lower respiratory tract disease and hospitalization. By providing season-long protection with a single dose, nirsevimab addresses the limitations of current prevention like palivizumab, which require frequent dosing. Its impact on reducing RSV-related hospitalizations and healthcare visits is vital for countries like Thailand, where seasonal peaks in RSV add pressure to healthcare resources. The broad approval of nirsevimab in several countries highlights its efficacy and safety, making it a crucial tool in the global effort to combat RSV. However, implementation should consider maternal vaccination status, infant age and risk factors, RSV seasonality, local recommendations, healthcare infrastructure, availability, and cost-effectiveness.

Thai pediatric experts emphasize that integrating a long-acting monoclonal antibody into routine infant care is a critical step in advancing RSV prevention, given its single-dose regimen and sustained protection of up to 180 days. During a recent expert discussion, specialists highlighted nirsevimab's potential to significantly reduce the RSV burden in infants, supported by its weight-based dosing strategy (50 mg for <5 kg, 100 mg for ≥ 5 kg, and 200 mg in the second season), which allows tailored protection.

Future directions

During the expert discussion, expansion of RSV prevention coverage, including consideration of broader infant populations, was discussed. Any expansion should be evaluated in the context of local epidemiology, clinical recommendations, programmatic feasibility, and health economic evidence. A coordinated approach, including healthcare provider education, government collaboration, public awareness initiatives, and pilot programs, was recommended to support implementation and address logistical challenges.

Optimizing RSV prevention requires continuous research, surveillance, and policy adaptation to ensure equitable access to effective interventions. Both maternal RSV vaccination and monoclonal antibodies provide meaningful benefits, though their cost-effectiveness varies by healthcare setting. Modeling studies suggest that nirsevimab prevents more RSV-related hospitalizations and bronchiolitis cases, while maternal vaccination may be more easily integrated into antenatal care in low-resource settings.

Future research should assess the long-term safety, effectiveness, and real-world performance of both strategies across diverse populations, particularly in low- and middle-income countries. Region-specific cost-effectiveness analyses, along with data on implementation challenges, uptake, and post-intervention RSV epidemiology, will be essential to inform national policies. Coordinated efforts among health authorities, researchers, and policymakers are critical to building sustainable RSV prevention frameworks that expand access, optimize implementation, and ensure financial feasibility.

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