

Effectiveness of Nirsevimab in preventing RSV (Respiratory Syncytial Virus) bronchiolitis

Thanks to a consortium coordinated by Prof. Naïm Ouldali (Hôpital Robert Debré, AP-HP; Inserm Unit IAME- UMR 1137, Université Paris Cité, Paris, France) and Prof. Camille Brehin (Toulouse University Hospital, Paul Sabatier University, Toulouse, France), a prospective multicentre study, promoted by the Centre Hospitalier Intercommunal de Créteil (Prof. Camille Jung), has been conducted to evaluate the real-life efficacy of nirsevimab in preventing RSV (respiratory syncytial virus) bronchiolitis in children under 12 months of age. This work, which is supported by ANRS MIE (ANRS0420) and involved teams from the AP-HP (Robert Debré, Armand Trousseau, Necker-Enfants malades and Jean Verdier hospitals), the Toulouse University Hospital and the Centre Hospitalier Intercommunal de Créteil (Créteil, France), was published in the [New England Journal of Medicine](#) on 10 July 2024.

Respiratory syncytial virus (RSV) is the main virus responsible for bronchiolitis, an infection of the lower respiratory tract affecting infants. This condition is by far the main cause of hospitalisation in children in France, leading to more than 26,000 paediatric hospitalisations every year. The winter of 2022-2023 was marked by an unusually intense RSV epidemic, which completely overwhelmed paediatric hospital and intensive care services.

Against this backdrop, in September 2023, France was one of the very first countries in the world to make Nirsevimab, a new RSV immunising antibody, available to infants nationwide. Assessing the effectiveness of this national immunisation campaign in preventing severe bronchiolitis was therefore a priority.

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This study, which involved numerous teams from the AP-HP (Robert Debré, Armand Trousseau, Necker-Enfants malades and Jean Verdier hospitals), the Toulouse University Hospital and the Centre Hospitalier Intercommunal de Créteil, included 1,035 infants hospitalised for RSV bronchiolitis (case group), or consulting the same hospitals for a pathology unrelated to RSV (control group). Nirsevimab was administered to 60 of the 690 patients in the case group (8.7%) and to 97 of the 345 patients in the control group (28.1%).

After more than 50 years of unsuccessful attempts to develop an RSV immunising treatment, this study highlights the major efficacy of a new preventive treatment, Nirsevimab, in preventing severe forms of RSV infection in young infants.

These large-scale results offer unique perspectives to preventing this infection. They will make it possible to launch a large-scale national immunisation programme to protect newborns and young infants from RSV infections every winter. It will be implemented at the start of the 2024-2025 school year.

The authors would like to thank ANRS MIE (Emerging infectious diseases) for funding this study, the Clinical research centre of the Centre Hospitalier Intercommunal de Créteil for promoting the study, the Paediatric infectious disease group of the French society of paediatrics, the Université Paris Cité, Inserm, and all the investigators and children who took part in this study.

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About AP-HP: Europe's leading university hospital centre (CHU), AP-HP and its 38 hospitals are organised into six university hospital groups (AP-HP. Centre – Université Paris Cité; AP-HP. Sorbonne University; AP-HP. Nord – Université Paris Cité; AP-HP. Université Paris-Saclay; AP-HP. Henri-Mondor University Hospitals and AP-HP. Hôpitaux Universitaires Paris Seine-Saint-Denis) and are structured around five Paris Region universities. In close collaboration with major research organisations, the AP-HP has eight world-class university hospital institutes (ICM, ICAN, IMAGINE, FOrSIGHT, PROMETHEUS, InovAND, Re-Connect, THEMA) and France's largest healthcare data warehouse (EDS). A major player in applied research and innovation in healthcare, the AP-HP holds a portfolio of 810 active patents, its clinician-researchers produce more than 11,000 scientific publications every year and nearly 4,400 research projects are currently under development, all sponsors included. In 2020, the AP-HP obtained the Carnot Institute label, which rewards the quality of its partnership research: the Carnot@AP-HP offers applied and clinical research solutions in the field of healthcare to industrial players. In 2015, the AP-HP also set up the Fondation de l'AP-HP, which works directly with healthcare professionals to support the organisation of care, hospital staff and research within the AP-HP. For more information: <https://www.aphp.fr/>

About ANRS MIE: ANRS MIE (Emerging Infectious Diseases) is an autonomous agency of Inserm (the French National Institute for Health and Medical Research). Its mission is to facilitate, evaluate, coordinate and fund research into HIV/AIDS, viral hepatitis, sexually transmitted infections, tuberculosis and emerging and re-emerging infectious diseases.

About Toulouse University Hospital: Toulouse University Hospital is a health and university institution in the city of Toulouse and the Occitanie region. As such, we fulfil our public service missions of care and prevention by treating all patients without discrimination, training the professionals of tomorrow, and contributing to innovation and health research. As the leading healthcare provider in the Occitanie region, we are the 4th largest hospital in France in terms of activity and one of the largest employers (16,000 professionals including 4,000 doctors and 12,000 hospital staff) in the region. Every year, around 300,000 patients are admitted to our hospitals, and we conduct around 1,000,000 patient consultations. In partnership with the Toulouse Faculty of Health Sciences and the PREFMS (Regional teaching and training centre for healthcare professions), we offer future hospital professionals cutting-edge training and a diverse working environment. We also contribute to the continuous improvement of care through research and innovation. Numerous successes, both medical advances and research projects, have made our university hospital centre a recognised campus of excellence.

About Hôpitaux Confluence Val-de-Marne Essonne: The Hôpitaux Confluence include the two historic hospitals of the Val-de-Marne: the Hôpital Intercommunal de Créteil and the Hôpital Intercommunal de Villeneuve-Saint Georges Lucie & Raymond Aubrac. Created in 2016, the Hôpitaux Confluence provide a first-class public health service in the Val-de-Marne and Essonne, serving a population of over 1.2 million inhabitants.

Key facts about the Hôpitaux Confluence Val-de-Marne Essonne:

- > More than 190,000 emergency room visits*
- > Nearly 5,400 births*
- > More than 22,000 surgical operations*
- > More than 585,000 consultations*
- > More than 260,000 hospital days*
- > 4,740 professionals, including nearly 680 medical professionals*
- > 1,203 beds*