

Trial of potential vaccine against serious RSV illness in babies shows valuable results

RSV Patient Network, 7 March 2019

RSV (Respiratory Syncytial Virus) is a very common virus which can cause serious respiratory infections in babies and young children. It is the most common cause of bronchiolitis and pneumonia (infections of the lungs) in children younger than 1 year of age. Sometimes, RSV infections can be very serious and require acute intensive care with mechanical ventilation. Thanks to high quality intensive care facilities the disease can be treated relatively well in high-income countries. However, on a global scale RSV is a leading cause of infant mortality. It is a major problem for which no vaccine or medicine is available.



Today, there are several RSV vaccines being developed in different parts of the world and chances are that a vaccine will become available in the next few years. Novavax is developing a vaccine for pregnant women and is most advanced in the lengthy and intensive drug development process. They are the first to have tested their vaccine on a large scale¹ during a multiannual trial.

On February 28th Novavax has announced the results from this trial in a [press release](#) and webcast. The RSV Patient Network has been looking forward to this with great interest. As parents of children that suffered from severe RSV disease we know all too well what impact this underestimated virus can have. With the availability of an effective vaccine much suffering could be prevented.

The Novavax trial shows some positive and encouraging results. The vaccine proves to be effective in protecting against severe cases of RSV infection in babies in their first three months of life (when the risk of severe infection is the highest). This is positive because these severe cases cause the most burden of disease. This vaccine could strongly reduce the number of RSV related hospitalisations, intensive care admissions and infant mortality rates. Moreover, trial results indicate that the vaccine is safe and well-tolerated by mother and child.

The Novavax trial did not meet its primary objective of prevention of medically significant RSV respiratory infections. However, further analysis of the trial results indicates that the vaccine's efficacy largely depends on the moment of administration during pregnancy. In the US, where the vaccine was administered relatively late², the vaccine was not effective, whereas in other parts of the world efficacy results were favourable. Additional research will have to show if the primary endpoint is met with better timing of vaccine administration.

¹ 4.636 pregnant women and their babies participated in this trial

² ≥ 33 weeks gestation in the US compared to ≤ 33 weeks gestation in other parts of the world

All in all, we believe this trial has produced much valuable information and has shown positive results on important aspects. Even though, the anticipated breakthrough did not happen, we are closer than ever to a vaccine. The Bill & Melinda Gates Foundation – who supported this trial in part by a grant of \$89 million – finds the results encouraging and believes it has great potential for reducing RSV-associated deaths in young babies. For Novavax the trial results are sufficient basis to meet with U.S. and European regulators and to discuss the path forward for licensure.



www.resvnet.org/patient-network



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