

Respiratory Syncytial Virus and Recurrent Wheeze in Healthy Preterm Infants

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BACKGROUND

Respiratory syncytial virus (RSV) infection is associated with subsequent recurrent wheeze. Observational studies cannot determine whether RSV infection is the cause of recurrent wheeze or the first indication of preexistent pulmonary vulnerability in preterm infants. The monoclonal antibody palivizumab has shown efficacy in preventing severe RSV infection in high-risk infants.

METHODS

In the double-blind, placebo-controlled MAKI trial, we randomly assigned 429 otherwise healthy preterm infants born at a gestational age of 33 to 35 weeks to receive either monthly palivizumab injections (214 infants) or placebo (215 infants) during the RSV season. The prespecified primary outcome was the total number of parent-reported wheezing days in the first year of life. Nasopharyngeal swabs were taken during respiratory episodes for viral analysis.

RESULTS

Palivizumab treatment resulted in a relative reduction of 61% (95% confidence interval, 56 to 65) in the total number of wheezing days during the first year of life (930 of 53,075 days in the RSV-prevention group [1.8%] vs. 2309 of 51,726 days [4.5%] in the placebo group). During this time, the proportion of infants with recurrent wheeze was 10 percentage points lower in patients treated with palivizumab (11% vs. 21%, $P=0.01$).

CONCLUSIONS

In otherwise healthy preterm infants, palivizumab treatment resulted in a significant reduction in wheezing days during the first year of life, even after the end of treatment. These findings implicate RSV infection as an important mechanism of recurrent wheeze during the first year of life in such infants. (Funded by Abbott Laboratories and by the Netherlands Organization for Health Research and Development; MAKI Controlled Clinical Trials number, [ISRCTN73641710](#).)