First European randomized trial confirms new pneumococcal vaccine highly effective in infants

15 November 2012

A new conjugate vaccine is highly effective (93%) at preventing invasive pneumococcal disease (IPD; meningitis, sepsis, bacteremic pneumonia, and other blood-borne infections) in infants younger than 2 years who are the most vulnerable to infection, according to new research published Online First in The Lancet. The nationwide study is the first to confirm the effectiveness of the three-dose (2+1) schedule that is already used in many national programs.

"Introduced in 2000, widespread use of the first PCV7 vaccine has significantly reduced the burden of IPD in children younger than 5 years. Our findings suggest that a series of three or four shots of the new PCV10 vaccine including three additional pneumococcal strains is going to work at least as well in preventing IPD, with the potential to prevent over 70% of severe pneumococcal disease cases in children worldwide", explains Arto Palmu from the National Institute for Health and Welfare in Finland, one of the lead authors.

The Finnish Invasive Pneumococcal Disease Vaccine Trial (FinIP) covered over three-quarters of the country. Nearly 46 000 children younger than 19 months were randomised to receive two to four doses of PCV10 (according to age) or hepatitis A or B vaccine as control. The researchers tracked the PCV10 vaccine's effectiveness over an mean 2-year period using the National Infectious Diseases Register.

The vaccine was designed to provide protection against 10 of the most common pneumococcal strains in children under 5 years.

They found that the PCV10 vaccine prevented 93% of cases of IPD in healthy infants who received at least one dose. Only one disease episode due to a serotype contained in the vaccine was detected shortly after the first vaccine dose compared with 12 in the control group. This translates to vaccine effectiveness of 92% against vaccine-type IPD for the three-dose (2+1) schedule and 100% for the four-dose (3 +1) schedule. No safety concerns were noted during the study.

According to Palmu, "This is the first clinical trial to confirm the excellent effectiveness of the recommended three-dose (2+1) schedule for infants already used in many national programmes as well as the clinical effectiveness of different catch-up immunisation schedules for older children."*

Writing in a linked Comment, Cynthia Whitney from the Centers for Disease Control and Prevention in the USA says, "[This trial] provide[s] confirmatory, conclusive evidence about the vaccine's benefits against invasive disease…[and] also provides helpful evidence that different vaccine schedules can be protective. This evidence base, along with resources for vaccine purchase for the poorest countries through the GAVI Alliance, support WHO's recommendation for use of these vaccines worldwide."

More information:
www.thelancet.com/journals/lan … (12)61854-6/abstract

Provided by Lancet