Immunogenicity Of DTaP-IPV-Hib And MenC Vaccines In The UK When Administered With a 13-valent Pneumococcal Conjugate Vaccine

C. L. BLASSER 1, G. D. HAYNE 1, J. Z. OH 1, J. LAYTON 1, S. DANIELS 2, S. TANSEY 2, D. SCOTT 2, S. BAKER 2, W. SNIDER 2, B. R. FAUST 1, S. PETRIDGE 1, A. FRINK 1, S. DUNN 1, P. T. HUGHES 1, S. JACOBY 1, K. J. MELLO 1

1 University of Oxford, UK, 2 Wyeth Vaccines, NY, NY

ABSTRACT

Background

Pneumococcal pneumonia is a leading cause of morbidity and mortality in children worldwide. Although the 7-valent pneumococcal conjugate vaccine (PCV7) has been successful in controlling pneumococcal disease, some pneumococcal serotypes are not covered by the vaccine. The effect of the lateral series results of a randomized, double-blind, placebo-controlled study of a 13-valent pneumococcal vaccine (PCV13), containing polysaccharides from serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F, and 33F individually conjugated to CRM197.

Methods

375 healthy infants aged 6-11 weeks were randomized 1:1 to receive PCV13 or PCV7 at 2 and 4 months. Participants received meningococcal C (MenC), tetanus, whole cell (Tet), and diphtheria, tetanus, acellular pertussis (DTaP) vaccines at 2, 3, and 4 months. Concomitant antibody responses in both groups and PCV7 responses in the PCV13 group were assessed at 3 months.

Results

Concomitant antibody responses were comparable in the 2 groups. Anti-PPV7 IgG concentration was 4.4-fold higher in the PCV13 group compared to the PCV7 group. MenC SBA titres of 1:8 were achieved by 99.2% of participants in both. All participants in both groups achieved anti-diphtheria and tetanus antibodies. PCV13 and PCV7 reactogenicity was comparable with comparable reactogenicity profiles.

Conclusions

Concomitant meningococcal vaccines is acceptable when administered with either PCV7 or PCV13 in a UK primary infant series.

INTRODUCTION

The 7-valent pneumococcal conjugate vaccine (PCV7) has successfully reduced invasive pneumococcal disease in the countries where it has been introduced.

- Significant disease causing serotypes, such as serotypes 1, 3 and 11A are not included in this vaccine, with a subsequent increase in the global pneumococcal disease burden.

- A novel 13-valent pneumococcal conjugate vaccine (PCV13) has been developed and tested in this multi-centre double-blind randomised controlled trial.

- The study was sponsored by Wyeth Vaccines.

OBJECTIVES

- To evaluate the proportion of participants achieving predetermined thresholds for concomitant antigens 1 month after the infant series.
- To evaluate the safety and reactogenicity of PCV13.
- To assess the antibody response of participants receiving 2 and 4 months courses of PCV13.

STUDY DESIGN

Dose 1   Dose 2

PCV13: 4.4 months
PCV7: 4.4 months
DTaP: 2, 3, 4 months

Concomitant serogroup C meningococcal (MenC) vaccine at age 2 months and DTaP-IPV-Hib vaccine at age 2, 3, and 4 months.

Immunogenicity of concomitant antigens is comparable when administered with either PCV7 or PCV13 in a UK infant series.

RESULTS

Percentage of participants achieving predetermined thresholds for concomitant antigens 1 month after the infant series.

Percentage of participants achieving predetermined thresholds for specific IgG concentrations.

ACKNOWLEDGMENTS

The authors thank the participants of this study and their families. They also wish to acknowledge the following co-investigators: Dr David Weston, Dr Malcolm McCaughey, Dr Timothy Hall, Dr Katrina Young, Dr Anthony Egerton.