Concomitant Use of VAQTA™ with PedvaxHIB™ and Infanrix™ in 12 to 17 Month Old Children

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Background

- Pertussis and Hib vaccines are administered to infants and children at 2, 4, and 6 months of age.
- Pertussis vaccine is also given at 12 to 15 months of age.
- There is no evidence that concomitant or non-concomitant administration of Pertussis vaccine alters antibody responses.

Study Design

- Clinical Assessment Schedule
- Vaccination and Blood Draw Timelines

Study Objectives

- To evaluate the safety and immunogenicity of all Hib vaccine administered concomitantly or non-concomitantly
- To evaluate the safety and immunogenicity of all Pertussis vaccine administered concomitantly or non-concomitantly

Statistical Methods

- Non-inferiority of the seroprotection rate (SPR) to hepatitis A corresponded to the lower bound of a 2-sided 95% CI on the difference (Group 1+3 minus Group 2+4), excluding a decrease of ≥10%

Results

- Pertussis PT Responses
- Hib Capsular PRP Antibody Responses

Conclusions

- In healthy children 12 to 17 months of age with a negative Hib antibody titer, VAQTA was administered concomitantly with DTaP and Hib vaccines without vaccine-related serious AEs being observed.
- VAQTA with Pertussis vaccine followed by Pertussis and Hib vaccines is safe and immunogenic.
- Pertussis vaccine administered concomitantly with VAQTA and Hib vaccines is safe.
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Definitely Not

- Pertussis vaccine administered concomitantly with VAQTA and Hib vaccines is safe.
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Relationship

- Pertussis vaccine administered concomitantly with VAQTA and Hib vaccines is safe.
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