Rusmil et al. BMC Pediatrics (2015) 15:219
DOI 10.1186/s12887-015-0525-2

BMC Pediatrics

RESEARCH ARTICLE Open Access

The immunogenicity, safety, and consistency of an Indonesia combined DTP-HB-Hib vaccine in expanded program on immunization schedule

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Abstract

Background: WHO recommended incorporation of *Haemophilus influenzae* type b (Hib) vaccination into immunization program. Indonesia would adopt Hib as a National Immunization Program in 2013. We aimed at analyzing immunogenicity, safety, and consistency of a new combined DTP-HB-Hib (diphtheria-tetanus-pertussis-Hepatitis B-Haemophilus influenza B) vaccine.

Methods: A prospective, randomized, double blind, multicenter, phase III study of Bio Farma DTP-HB-Hib vaccine conducted in Jakarta and Bandung, August 2012 - January 2013.
Subjects were divided into three groups with different batch number. Healthy infants 6–11 weeks of age at enrollment were immunized with 3 doses of DTP-HB-Hib vaccine with interval of 4 weeks, after birth dose of hepatitis B vaccine. Blood samples obtained prior to vaccination and 28 days after the third dose. Safety measures recorded until 28 days after each dose.

Results: Of 600 subjects, 575 (96 %) completed study protocol. After 3 doses, 100.0 and 96.0 % had anti-PRP concentration ≥0.15 and ≥1.0 μg/ml. Anti-diphtheria and anti-tetanus concentration ≥0.01 IU/ml detected in 99.7 and 100.0 %; while concentration ≥0.1 IU/ml achieved in 84.0 and 97.4 %. Protective anti-HBs found in 99.3 %. The pertussis vaccine response rate was 84.9 %.
None Serious Adverse events (SAEs) considered related to study vaccine or procedure.

Conclusions: The 3-dose of DTP-HB-Hib was immunogenic, well tolerated and suitable for replacement of licensed-equivalent vaccines based on immunologic and safety profiles.

Trial registration: NCT01986335 – October 30th 2013.

Keywords: Combined DTP-HB-Hib vaccine, Infants, Primary vaccination, EPI

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