We evaluated the immunogenicity and reactogenicity of diphtheria, tetanus, whole-cell pertussis and hepatitis B (DTPw-HB) combination vaccine manufactured by Shantha Biotechnics Pvt Ltd, Hyderabad, India in healthy infants between 6 and 8 weeks of age.

Overall 123 infants (male:female ratio, 1:1.3) were recruited, of which 112 received all three doses of the vaccine at 6, 10 and 14 weeks of age. Parents or guardians were given diary cards for recording adverse reactions. Blood samples were taken prior to and 4–6 weeks after the final vaccination dose. Anti-diphtheria, pertussis, and tetanus antibodies were assayed using solid phase immunoassay (NovaTec Immundiagnostica, Germany) while hepatitis B antibodies were determined by sandwich ELISA (Biokit, Spain) while hepatitis B antibodies were determined by sandwich ELISA (Biokit, Spain).

All 112 infants (100 per cent) had protective titers of anti-diphtheria antibodies (≥0.1 IU/ml, GMT 2.02 mIU/ml), while protective anti-Hb (≥10 mIU/ml, GMT 2108.7 IU/ml) and anti-tetanus (≥0.1 IU/ml, GMT 1.86 IU/ml) titers were seen in 99.1 per cent subjects. Although all vaccinated infants developed anti-pertussis antibodies titers ≥11 NTU/ml (assay cut-off), positive response to the Bordetella pertussis component of the vaccine was considered if the post-vaccination titers were greater than the pre-vaccination values,1 which was observed in 86.6 per cent (97 of 112) infants. The most frequently observed adverse events were mild fever (76.1 per cent), swelling at the injection site (40.1 per cent), pain (33.8 per cent), redness (23.7 per cent), and irritability (14.2 per cent).

This indigenous DTPw-HB combination vaccine induced a strong immune response and has not had any effect on the immunogenicity of the hepatitis B component or vice versa. It also fulfills the WHO recommendation of at least 95 per cent seroprotection against hepatitis B after three doses of the vaccine.2 The reactogenicity and immunogenicity profile are also in agreement with results obtained in studies carried out in Lithuania, Greece, and Thailand.1,3,4

References

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