These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription.

Sponsor: Sanofi **Drug substance(s):** DTPwHB-Hib combination vaccine (SHAN 5®)	**Study Identifiers:** NCT00617812 **Study code:** DTPwHB-Hib/PMS/2007/010
Title of the study: An Open label Multicentric Study to evaluate the Immunogenicity and Safety of indigenously developed DTPwHB-Hib (Liquid) Pentavalent combination Vaccine (SHAN 5®) in Indian Infants	
Study center(s): Four centers in India	
Study period: Date first subject enrolled: 13/Mar/2008 Date last subject completed: 29/Dec/2008	
Phase of development: Phase 4	
Objectives: The objective of this study was to determine the Immunogenicity and Safety of Indigenously developed pentavalent vaccine (SHAN 5®)	
Methodology: Single Arm, Multicentric, Prospective, Open label, Non-Comparative trial.	
Number of subjects: Planned: 160 Randomized: 160 Treated: 160 **Evaluated:** Safety: 160 Immunogenicity: 151	
Diagnosis and criteria for inclusion: Inclusion Criteria • Healthy children in the age group six to eight weeks • Born after a normal gestational period (36 - 42 weeks) • Mother's HBsAg assured negative. • Father, mother or legally acceptable representative properly Informed about the study and having signed the informed consent form • Parents willing to fill the Diary Card	
Study treatment **Investigational medicinal product:** Formulation: Liquid Route(s) of administration: Deep intramuscular injection, preferably in the anterolateral thigh Dose regimen: Three doses of 0.5 mL each at the age of 4 to 6 weeks, 10 to 12 weeks and 14 to 16 weeks	

Duration of treatment: 12 weeks

Duration of observation: 30 minutes to 3 hours after each dose

Criteria for evaluation:

Safety:

Assessment of adverse events after every dose of vaccine administered

Immunogenicity:

Monitoring the humoral immune response induced by each Component i.e. diphtheria, tetanus, pertussis, hepatitis-B and Hib before the first dose and four to six weeks after the last dose of vaccines in all subjects.

Statistical methods:

Descriptive statistics such as number, mean, median, standard deviation and range (minimum, maximum) were used for summarizing the continuous variables. Frequencies and relative frequencies were computed for categorical data. Graphs like histograms, line charts, pie charts, etc were generated wherever necessary. Concentrations of antibodies were log transformed, and geometric mean antibody concentrations (GMCs) compared using analysis of variance (ANOVA). The proportions of participants who responded to each of the vaccine antigens were compared using Chi-square. Analysis of safety was performed on the total vaccinated cohort. The percentages of infants experiencing a symptom within 3 days following vaccination was computed with the exact 95% CI, according to the type and intensity of the symptom and its relationship to vaccine. Occurrence rates of adverse reactions (after each dose and overall for all the three groups and center wise) were compared using Chi-square or Fisher's exact tests. Geometric Mean Antibody Concentrations at pre-immunization and post-immunization were compared using paired t-test.

Summary:

Population characteristics:

Overall 160 subjects were recruited at different centers, of these subjects 151 were evaluable as per protocol for immunogenicity whereas all 160 were available for safety.

Safety results:

Local pain at the site of injection was the most common local adverse events following immunization (AEFI) followed by local swelling and redness. The incidence of all these local AEFIs decreased with each subsequent dose of the vaccine though the hierarchal relationship between the three was maintained.

Among the systemic AEFIs mild fever following vaccination was the most commonly reported event followed by crying. Fever was mostly mild in nature and subsided on its own. The incidence of fever decreased with the subsequent doses of the vaccine.

There were no SAEs reported in the study.

Immunogenicity results:

There was 100% seroconversion for anti diphtheria antibodies and anti tetanus antibodies. Seroconversion to anti HBS antibodies was seen in 99.34% of infants after vaccination with three doses. There was 59.60% seroconversion for anti-pertussis antibodies. Anti Hib antibodies were associated with 100% seroconversion for short term protection (titers > 0.15 µg/mL) and 96.03% seroconversion signifying long term protection (titers > 1.0 µg/mL).

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