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Study No.: 208108/059 (Hib-059)			
Title: A post-marketing surveillance study of GlaxoSmithKline Biologicals' <i>Haemophilus influenzae</i> type b (Hib) tetanus conjugate vaccine in 3,000 Filipino subjects.			
Rationale: The aim of the study was to assess the safety of <i>Haemophilus influenzae</i> type b (Hib) tetanus conjugate vaccine in 3,000 Filipino subjects.			
Phase: IV			
Study Period: 27 November 1997 to 28 December 2002			
Study Design: A multicentric, post-marketing surveillance study of Hib tetanus conjugate vaccine administered according to the Prescribing Information (PI) of the Philippines.			
Centers: Sixty-six centers in the Philippines.			
Indication: Active immunization against influenza type b and tetanus diseases of healthy children.			
Treatment: The study groups were as follows: <ul style="list-style-type: none"> • Group 1: subjects aged \leq 6 months at the time of the first vaccination, received 3 doses of vaccine, given at 2, 4 and 6 months; a booster dose was given in the second year of life. • Group 2: subjects aged $>$ 6 months to \leq 1 year at the time of the first vaccination received 2 doses of vaccine given at a 1-month interval and a booster dose in the second year of life. • Group 3: subjects aged $>$1 to 5 years, at the time of the first vaccination received 1 dose of vaccine. • All vaccines were administered by deep intramuscular injection into the left anterolateral thigh. 			
Objectives: To assess the safety of a <i>Haemophilus influenzae</i> type b tetanus conjugate vaccine in 3,000 healthy Filipino subjects.			
Primary Outcome/Efficacy Variable: Safety of Hib vaccine was assessed by recording adverse events (AEs) noted by the prescribing physician or spontaneously/ retrospectively by the parent/ guardian.			
Secondary Outcome/Efficacy Variable(s): Not Applicable			
Statistical Methods: The analyses were performed on the Total Vaccinated cohort. The Total Vaccinated cohort included all subjects who received at least one dose of the study vaccine, for whom age could be calculated and had no irresolvable data discrepancies. <i>Analysis of safety:</i> The analysis of safety was performed on the Total Vaccinated cohort. For each solicited symptom, the percentage of subjects with the symptom was summarized for Dose 1, for Dose 2 and across all doses with their 95% confidence interval (CI). The percentage of subjects with unsolicited AEs occurring one month (minimum 30 days) post-vaccination was tabulated according to the World Health Organization (WHO) preferred term for each group. The occurrence of serious adverse events (SAEs) was tabulated according to the WHO preferred term for each group throughout the entire study period.			
Study Population: Primary vaccination of healthy infants and children \leq 6 months to 5 years of age. Written informed consent was obtained from the parents/guardians of the subjects prior to study entry.			
Number of Subjects:	Group 1	Group 2	Group 3
Planned, N	3000 (total subjects)		
Randomized, N (Total Vaccinated cohort)	2189*	267*	722*
Completed, n (%)	2120 (96.8)	255 (95.5)	713 (98.8)
Total Number Subjects Withdrawn, n (%)	69 (3.2)	12 (4.5)	9 (1.2)
Withdrawn due to Adverse Events, n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Withdrawn due to Lack of Efficacy, n (%)	Not Applicable	Not Applicable	Not Applicable
Withdrawn for other reasons, n (%)	69 (3.2)	12 (4.5)	9 (1.2)
Demographics	Group 1	Group 2	Group 3
N (Total Vaccinated cohort)	2189	267	722
Females: Males	1032:1155**	121:146	334:388
Mean Age, month (SD)	3.0 (1.30)	9.3 (1.87)	24.3 (10.70)

Race, n (%)	Not Applicable				Not Applicable				Not Applicable			
<p>* 3206 subjects were vaccinated. Out of these, 28 subjects were removed from the Total vaccinated cohort because date of birth or one of the 3 visit dates were incompatible (inconsistency in the chronology) and the correct values could not be obtained. This gives a final total of 3178 vaccinated subjects in the Total vaccinated cohort which was analyzed.</p> <p>** The gender of 2 subjects was not reported</p>												
Primary Efficacy Results:												
Number and percentage of subjects for whom solicited symptoms* were reported after each vaccine dose† and across doses (Total Vaccinated cohort)												
Symptom	Group 1				Group 2				Group 3			
	n	%	95% CI		n	%	95% CI		n	%	95% CI	
			LL	UL			LL	UL			LL	UL
Dose 1												
N = 2189												
N = 267												
N = 722												
Pain	8	0.37	0.16	0.72	1	0.37	0.01	2.07	2	0.28	0.03	1.00
Redness	26	1.19	0.78	1.74	0	0.00	0.00	1.37	4	0.55	0.15	1.41
Swelling	7	0.32	0.13	0.66	0	0.00	0.00	1.37	0	0.00	0.00	0.51
Fever (≥37.5°C)	23	1.05	0.67	1.57	2	0.75	0.09	2.68	3	0.42	0.09	1.21
Other	14	0.64	0.35	1.07	1	0.37	0.01	2.07	3	0.42	0.09	1.21
Dose 2												
N = 2123												
N = 190												
N = 37												
Pain	7	0.33	0.13	0.68	0	0.00	0.00	1.92	0	0.00	0.00	9.49
Redness	23	1.08	0.69	1.62	0	0.00	0.00	1.92	1	2.70	0.07	14.16
Swelling	2	0.09	0.01	0.34	0	0.00	0.00	1.92	0	0.00	0.00	9.49
Fever (≥37.5°C)	27	1.27	0.84	1.85	0	0.00	0.00	1.92	1	2.70	0.07	14.16
Other	15	0.71	0.40	1.16	0	0.00	0.00	1.92	0	0.00	0.00	9.49
Across Doses												
N = 2189												
N = 267												
N = 722												
Pain	10	0.46	0.22	0.84	1	0.37	0.01	2.07	2	0.28	0.03	1.00
Redness	27	1.23	0.81	1.79	0	0.00	0.00	1.37	4	0.55	0.15	1.41
Swelling	7	0.32	0.13	0.66	0	0.00	0.00	1.37	0	0.00	0.00	0.51
Fever (≥37.5°C)	40	1.83	1.31	2.48	2	0.75	0.09	2.68	4	0.55	0.15	1.41
Other	27	1.23	0.81	1.79	1	0.37	0.01	2.07	3	0.42	0.09	1.21
<p>N: Number of subjects with at least one symptom completed sheet</p> <p>n(%): Number (percentage) of subjects for whom a specific symptom was reported</p> <p>95% CI: exact confidence interval; LL: Lower limit; UP: Upper limit</p> <p>* No follow-up was defined for this study</p> <p>† Only safety data concerning post-dose 1 and post-dose 2 were collected</p> <p>'Other' symptoms included cough, cold, rash, fever etc.</p>												
Secondary Outcome Variable(s):												
Not Applicable												
Safety Results: Number (%) of subjects with unsolicited Adverse Events (Total Vaccinated cohort)												
Most Frequent Adverse Events - On-Therapy- (occurring within Day 0-30 following vaccination)	Group 1				Group 2				Group 3			
	N = 2189				N = 267				N = 722			
Subjects with any AE(s), n (%)	68 (3.1)				2 (0.8)				9 (1.3)			
Injection site reaction	30 (1.4)				0 (0.0)				6 (0.8)			
Fever	28 (1.3)				1 (0.4)				2 (0.3)			
Coughing	20 (0.9)				1 (0.4)				1 (0.1)			
Upper respiratory tract infection	11 (0.5)				0 (0.0)				1 (0.1)			
Diarrhea	4 (0.2)				0 (0.0)				0 (0.0)			
Pharyngitis	3 (0.1)				0 (0.0)				0 (0.0)			
Vomiting	2 (0.1)				0 (0.0)				1 (0.1)			
Asthma	2 (0.1)				0 (0.0)				0 (0.0)			
Rash	1 (0.0)				0 (0.0)				1 (0.1)			
Rhinitis	2 (0.1)				0 (0.0)				0 (0.0)			
Anorexia	1 (0.0)				0 (0.0)				0 (0.0)			

Dehydration	1 (0.0)	0 (0.0)	0 (0.0)
Injection site pain	0 (0.0)	0 (0.0)	1 (0.1)
Pain	1 (0.0)	0 (0.0)	0 (0.0)
Rash maculo-papular	1 (0.0)	0 (0.0)	0 (0.0)
Rash pustular	1 (0.0)	0 (0.0)	0 (0.0)
Urinary tract Infection	1 (0.0)	0 (0.0)	0 (0.0)
Safety Results: Number (%) of subjects with Serious Adverse Events (SAEs) during the entire study period (Total Vaccinated cohort)			
Serious adverse event, n (%) [n considered by the investigator to be related to study medication]			
All SAEs	Group 1 N = 2189	Group 2 N = 267	Group 3 N = 722
Subjects with any SAE(s), n (%) [related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	Group 1 N = 2189	Group 2 N = 267	Group 3 N = 722
Subjects with fatal SAEs, n (%) [related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Conclusion:

Fever was the most frequently occurring post-vaccination solicited symptom in all 3 age groups & was reported in 1.83% of subjects in Group 1, 0.75% of subjects in Group 2 and 0.55% of subjects in Group 3. Unsolicited adverse events were reported in 3.1% of subjects in Group 1, 0.8% of subjects in Group 2 and 1.3% of subjects in Group 3. No SAE was reported.

Publications: No Publication

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