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Study No.: 208140/038 (DTPa-HBV-038)
Title: Open, randomised clinical study to assess the immunogenicity and reactogenicity of SB Biologicals' DTPa HBV and Hib, either mixed in one syringe (formulation B), or given at the same visit in two concomitant injections into opposite limbs (formulation A & B), as a primary vaccination course to healthy infants at the age of 2, 4 and 6 months. DTPa-HBV: GlaxoSmithKline (GSK) Biologicals' (Smith KlineBeecham [SB]) combined diphtheria, tetanus, acellular pertussis, hepatitis B vaccine. Hib: GSK Biologicals' <i>Haemophilus influenzae</i> type b vaccine.
Rationale: The aim of this study was to evaluate the immunogenicity and safety of DTPa-HBV vaccine when administered, separately or mixed, with different formulations (formulation 1 and formulation 2) of Hib vaccine.
Phase: III
Study Period: 28 June 1996 to 27 August 1997.
Study Design: Open, randomised, multi-centre study with 3 groups (1:1:1).
Centres: 6 centres in Switzerland.
Indication: Immunisation against diphtheria, tetanus, pertussis, hepatitis B and <i>Haemophilus influenzae</i> type b diseases in healthy infants.
Treatment: The study groups were as follows: <ul style="list-style-type: none"> • DTPa-HBV+ Hib F1 Group: received simultaneous intramuscular administration of DTPa-HBV vaccine in the left anterolateral thigh and Hib (formulation 1; commercially available formulation) vaccine in the right anterolateral thigh. • DTPa-HBV+ Hib F2 Group: received simultaneous intramuscular administration of DTPa-HBV vaccine in the left anterolateral thigh and Hib (formulation 2) vaccine in the right anterolateral thigh. • DTPa-HBV/Hib Group: received reconstituted intramuscular administration of DTPa-HBV and Hib (formulation 2) in the left anterolateral thigh.
Objectives: To evaluate the immunogenicity of the Hib polysaccharide polyribosyl-ribitol-phosphate (PRP) in terms of anti-PRP concentration distribution (concentrations ≥ 0.15 , ≥ 0.5 and ≥ 1.0 $\mu\text{g}/\text{mL}$, and geometric mean concentrations (GMCs) in all groups.
Primary Outcome/Efficacy Variable: <ul style="list-style-type: none"> • Percentage of subjects with anti-PRP concentrations ≥ 1.0 $\mu\text{g}/\text{mL}$ one month after the third dose of the primary vaccination course.
Secondary Outcome/Efficacy Variable(s): <ul style="list-style-type: none"> • For anti-PRP, percentages of subjects with anti-PRP concentrations ≥ 0.15 $\mu\text{g}/\text{mL}$, ≥ 0.5 $\mu\text{g}/\text{mL}$ and ≥ 1 $\mu\text{g}/\text{mL}$, and GMCs one month after the third dose of the primary vaccination course. • For anti-hepatitis B surface antigen (anti-HBs), percentages of subjects with concentrations ≥ 10 mIU/mL, and GMCs one month after the third dose of the primary vaccination course. • For the three pertussis markers, pertussis toxin (PT), filamentous haemagglutinin (FHA), pertactin (PRN), percentages of subjects showing a vaccine response (defined as the appearance of antibodies in initially seronegative subjects or a post vaccination concentration greater than or equal to the pre-vaccination concentration in initially seropositive subjects) and GMCs one month after the third dose of the primary vaccination course. • For anti-diphtheria and anti-tetanus, percentages of subjects with concentrations ≥ 0.1 IU/mL, and GMCs one month after the third dose of the primary vaccination course. • Incidence, nature and relationship of solicited and unsolicited symptoms in each group. • Incidence, nature and relationship of serious adverse events (SAEs) in each group.

Statistical Methods:

The analyses were performed on the Total Vaccinated Cohort and According-To-Protocol (ATP) cohort for immunogenicity and ATP cohort for safety.

- The Total Vaccinated Cohort included all subjects with study vaccine administered.
- The ATP cohort for safety included all subjects who received the study vaccine according to protocol, with safety follow-up and who did not receive vaccine forbidden as per protocol.
- The ATP cohort for immunogenicity included all who had post-vaccination immunogenicity results and who complied with the protocol, including the time schedule for vaccination and blood sample draw.

Analysis of Immunogenicity:

The analysis of immunogenicity was performed on the ATP cohort for immunogenicity. GMC and seroprotection/seropositivity rates were calculated with their 95% confidence interval (CI) for each antibody measured at each blood sampling time point. Antibody concentrations below the assay cut-off were given an arbitrary value of one half of the cut-off value.

Analysis of Safety

The analyses of safety were performed on the ATP cohort for safety or the Total Vaccinated Cohort. The percentage of subjects with each individual solicited local and general symptom during the 4-day (Day 0-3) solicited follow-up period was tabulated with its 95% CI. The same tabulation was performed for Grade 3 symptoms and for solicited general symptoms with certain or possible relationship to vaccination. The percentage of subjects with any at least one report of unsolicited adverse events (AEs) classified according to World Health Organization (WHO) preferred terms after vaccination was tabulated by group. The occurrence of serious adverse events (SAEs) during the entire study period was tabulated.

Study Population: Healthy infants between 8 and 12 weeks of age at the time of first vaccination. Subjects with evidence of diphtheria, tetanus, pertussis, hepatitis B and/or *Haemophilus influenzae* type b vaccination or disease were excluded. Written informed consent was obtained from the parents/guardians of the subject.

Number of subjects				DTPa-HBV+ Hib F1 Group	DTPa-HBV+ Hib F2 Group	DTPa-HBV/Hib Group			
Planned, N				160	160	160			
Randomised, N (Total Vaccinated Cohort)				159	155	157			
Completed, n (%)				156 (98.1)	152 (98.1)	153 (97.5)			
Total Number Subjects Withdrawn, n (%)				3 (1.9)	3 (1.9)	4 (2.5)			
Withdrawn due to Adverse Events, n (%)				0 (0.0)	0 (0.0)	2 (1.3)			
Withdrawn due to Lack of Efficacy, n (%)				Not Applicable	Not Applicable	Not Applicable			
Withdrawn for other reasons, n (%)				3 (1.9)	3 (1.9)	2 (1.3)			
Demographics				DTPa-HBV+ Hib F1 Group	DTPa-HBV+ Hib F2 Group	DTPa-HBV/Hib Group			
N (Total Vaccinated Cohort)				159	155	157			
Females: Males				69:90	76:79	82:75			
Mean Age, weeks (SD)				9.4 (1.46)	9.6 (2.44)	9.1 (1.34)			
White/Caucasian, n (%)				146 (91.8)	141 (91.0)	145 (92.4)			
Primary Efficacy Results:									
Anti-PRP seropositivity, seroprotection rates and GMCs (ATP analysis of immunogenicity)									
Timing	N	≥ 0.15g/mL	%	95% CI (LL-UL)	≥ 1g/mL*	%	95% CI (LL-UL)	GMC (g/mL)	95% CI (LL-UL)
DTPa-HBV+ Hib F1 Group									
Pre	102	38	37.3	27.4-47.1	5	4.9	1.8-11.6	0.143	0.119-0.173

Post III	104	102	98.1	92.5-99.7	92	88.5	80.3-93.6	4.320	3.344-5.581
DTPa-HBV+ Hib F2 Group									
Pre	91	35	38.5	27.9-49.0	5	5.5	2.0-12.9	0.157	0.125-0.196
Post III	98	98	100	95.3-100	85	86.7	78.0-92.5	3.459	2.726-4.390
DTPa-HBV/Hib Group									
Pre	92	31	33.7	23.5-43.9	4	4.3	1.4-11.4	0.131	0.109-0.157
Post III	100	100	100	95.4-100	86	86.0	77.3-91.9	2.941	2.405-3.596
N = total number of subjects for whom a result exists (included in ATP) Pre/Post III = pre-vaccination/ approximately one month after Dose 3 95% CI = 95% Confidence Interval ; LL= Lower Limit, UL= Upper Limit * Primary Efficacy Variable									
Secondary Outcome Variable(s): Distribution of anti-PRP concentrations (ATP analysis of immunogenicity)									
Group	Timing	N	≥ 0.15 µg/mL		≥ 0.5 µg/mL		≥ 1.0 µg/mL		
			n	%	n	%	n	%	
DTPa-HBV+ Hib F1	Pre	102	38	37.3	15	14.7	5	4.9	
	Post III	104	102	98.1	99	95.2	92	88.5	
DTPa-HBV+ Hib F2	Pre	91	35	38.5	17	18.7	5	5.5	
	Post III	98	98	100	92	93.9	85	86.7	
DTPa-HBV/Hib	Pre	92	31	33.7	12	13.0	4	4.3	
	Post III	100	100	100	97	97.0	86	86.0	
N = total number of subjects for whom a result exists n = number of subjects with a concentration within a given range Pre/Post III = pre-vaccination/ approximately one month after Dose 3									
Secondary Outcome Variable(s): Anti-HBs seropositivity rates (%) and GMCs (ATP analysis of immunogenicity)									
Timing	N	S+	%	95% CI (LL-UL)		GMC (mIU/mL)	95% CI (LL-UL)		
DTPa-HBV+ Hib F1 Group									
Pre	106	19	17.9	11.4-26.8		10.1	7.4-13.9		
Post III	103	100	97.1	91.1-99.2		700.9	519.2-946.1		
DTPa-HBV+ Hib F2 Group									
Pre	93	15	16.1	9.6-25.5		9.0	6.5-12.3		
Post III	96	93	96.9	90.5-99.2		1094.1	804.6-1487.7		
DTPa-HBV/Hib Group									
Pre	89	6	6.7	2.8-14.6		6.8	5.3-8.7		
Post III	100	98	98.0	92.3-99.7		744.0	555.4-996.7		
N = total number of subjects for whom a result exists (included in ATP) S+: Number of subjects with a concentration ≥10 mIU/mL at a particular time point Pre/Post III = pre-vaccination/ approximately one month after Dose 3 95% CI = 95% confidence interval ; LL= Lower Limit, UL= Upper Limit									
Secondary Outcome Variable(s): Vaccine response to pertussis components (ATP analysis of immunogenicity)									
Antibody	Group		Pre-vaccination status		Vaccine response (Post)				
			Pre	N	n	%	95% CI (LL-UL)		

Anti-PT	DTPa-HBV+ Hib F1	S-	71	71	100	
		S+	33	26	78.8	
		Total	104	97	93.3	86.2-97.0
	DTPa-HBV+ Hib F2	S-	62	62	100	
		S+	33	33	100	
		Total	95	95	100	95.2-100
	DTPa-HBV/Hib	S-	75	75	100	
		S+	27	24	88.9	
		Total	102	99	97.1	91.1-99.3
Anti-FHA	DTPa-HBV+ Hib F1	S-	13	13	100	
		S+	85	84	98.8	
		Total	98	97	99.0	93.7-100
	DTPa-HBV+ Hib F2	S-	14	14	100	
		S+	73	73	100	
		Total	87	87	100	94.7-100
	DTPa-HBV/Hib	S-	17	17	100	
		S+	75	73	97.3	
		Total	92	90	97.8	91.6-99.6
Anti-PRN	DTPa-HBV+ Hib F1	S-	66	66	100	
		S+	39	39	100	
		Total	105	105	100	95.6-100
	DTPa-HBV+ Hib F2	S-	67	67	100	
		S+	30	28	93.3	
		Total	97	95	97.9	92.0-99.6
	DTPa-HBV/Hib	S-	68	68	100	
		S+	34	33	97.1	
		Total	102	101	99.0	93.8-99.9

S- = pre-vaccination seronegative subjects for the corresponding antibody
S+ = pre-vaccination seropositive subjects for the corresponding antibody
N = number of subjects with a particular pre-vaccination status
n = number of subjects with a vaccine response
95% CI = 95% confidence interval ; LL= Lower Limit, UL= Upper Limit

Secondary Outcome Variable(s):

Anti-PT seropositivity rates (%) and GMCs (ATP analysis of immunogenicity)

Timing	N	S+	%	95% CI (LL-UL)	GMC (EL.U/mL)	95% CI (LL-UL)
DTPa-HBV+ Hib F1 Group						
Pre	104	34	31.8	22.5-41.1	4.1	3.5-4.9
Post III	104	104	100	95.7-100	42.1	37.3-47.5
DTPa-HBV+ Hib F2 Group						
Pre	96	33	34.4	24.4-44.4	3.9	3.4-4.4
Post III	97	97	100	95.3-100	44.7	39.8-50.3
DTPa-HBV/Hib Group						
Pre	102	27	26.5	18.5-36.3	3.7	3.2-4.3
Post III	103	103	100	95.5-100	39.2	35.1-43.9

N = total number of subjects for whom a result exists
S+: Number of subjects with concentrations \geq 5EL.U/mL at a particular time point
Pre/Post III = pre-vaccination/ approximately one month after Dose 3
95% CI = 95% Confidence Interval ; LL= Lower Limit, UL= Upper Limit

Secondary Outcome Variable(s):

Anti-FHA seropositivity rates (%) and GMCs (ATP analysis of immunogenicity)

Timing	N	S+	%	95% CI (LL-UL)	GMC (EL.U/mL)	95% CI (LL-UL)
DTPa-HBV+ Hib F1 Group						
Pre	101	86	85.1	76.4-91.2	14.1	11.5-17.2
Post III	107	107	100	95.7-100	338.6	296.8-386.3
DTPa-HBV+ Hib F2 Group						
Pre	87	73	83.9	74.1-90.6	15.5	12.5-19.1
Post III	97	97	100	95.3-100	303.9	265.5-347.9
DTPa-HBV/Hib Group						
Pre	92	75	81.5	71.8-88.6	13.8	11.1-17.2
Post III	103	103	100	95.5-100	299.6	264.6-339.3

N = total number of subjects for whom a result exists

S+: Number of subjects with concentrations \geq 5EL.U/mL at a particular time point

Pre/Post III = pre-vaccination/ approximately one month after Dose 3

95% CI = 95% Confidence Interval ; LL= Lower Limit, UL= Upper Limit

Secondary Outcome Variable(s):

Anti-PRN seropositivity rates (%) and GMCs (ATP analysis of immunogenicity)

Timing	N	S+	%	95% CI (LL-UL)	GMC (EL.U/mL)	95% CI (LL-UL)
DTPa-HBV+ Hib F1 Group						
Pre	108	39	36.1	26.6-45.6	4.2	3.6-4.9
Post III	107	107	100	95.7-100	194.9	169.3-224.3
DTPa-HBV+ Hib F2 Group						
Pre	98	30	30.6	21.0-40.2	4.2	3.5-5.0
Post III	97	97	100	95.3-100	205.4	176.3-239.3
DTPa-HBV/Hib Group						
Pre	102	34	33.3	23.7-43.0	4.2	3.6-5.0
Post III	103	103	100	95.5-100	190.7	168.4-215.9

N = total number of subjects for whom a result exists

S+: Number of subjects with concentrations \geq 5EL.U/mL at a particular time point

Pre/Post III = pre-vaccination/ approximately one month after Dose 3

95% CI = 95% Confidence Interval ; LL= Lower Limit, UL= Upper Limit

Secondary Outcome Variable(s):

Anti-diphtheria seropositivity rates (%) and GMCs (ATP analysis of immunogenicity)

Timing	N	S+	%	95% CI (LL-UL)	GMC (IU/mL)	95% CI (LL-UL)
DTPa-HBV+ Hib F1 Group						
Pre	106	42	39.6	29.8-49.4	0.107	0.088-0.131
Post III	107	105	98.1	92.8-99.7	1.531	1.281-1.830
DTPa-HBV+ Hib F2 Group						
Pre	98	37	37.8	27.6-47.9	0.104	0.083-0.129
Post III	97	97	100	95.3-100	1.777	1.503-2.102
DTPa-HBV/Hib Group						
Pre	99	43	43.4	33.2-53.7	0.105	0.086-0.127
Post III	103	103	100	95.5-100	1.617	1.385-1.889

N = total number of subjects for whom a result exists, included in ATP

S+: Number of subjects seropositive at a particular time point

Pre/Post III = pre-vaccination/ approximately one month after Dose 3

95% CI = 95% Confidence Interval ; LL= Lower Limit, UL= Upper Limit

Secondary Outcome Variable(s):

Anti-tetanus seropositivity rates (%) and GMCs (ATP analysis of immunogenicity)

Timing	N	S+	%	95% CI (LL-UL)	GMC (IU/mL)	95% CI (LL-UL)
DTPa-HBV+ Hib F1 Group						
Pre	108	87	80.6	71.6-87.3	0.501	0.380-0.659
Post III	107	107	100	95.7-100	1.789	1.514-2.115
DTPa-HBV+ Hib F2 Group						
Pre	98	71	72.4	62.3-80.8	0.394	0.289-0.537
Post III	97	97	100	95.3-100	2.902	2.522-3.339
DTPa-HBV/Hib Group						
Pre	101	83	82.2	73.0-88.8	0.479	0.367-0.625
Post III	103	103	100	95.5-100	1.906	1.669-2.176

N = total number of subjects for whom a result exists, included in ATP

S+: Number of subjects seropositive at a particular time point

Pre/Post III = pre-vaccination/ approximately one month after Dose 3

95% CI = 95% Confidence Interval ; LL= Lower Limit, UL= Upper Limit

Secondary Outcome Variable(s):

Incidence of local solicited signs and symptoms reported during the 4-day (Day 0-3) post-vaccination period, including those graded with maximum intensity (ATP analysis of safety)

Symptom	Injection site	Intensity	DTPa-HBV+ Hib F1 Group		DTPa-HBV+ Hib F2 Group		DTPa-HBV/Hib Group	
			N = 431		N = 409		N = 420	
			n	%	n	%	n	%
Pain	DTPa-HBV/Hib	Any	-	-	-	-	61	14.5
		Grade 3	-	-	-	-	6	1.4
	DTPa-HBV	Any	59	13.7	53	13.0	-	-
		Grade 3	4	0.9	1	0.2	-	-
	HIB form 1	Any	37	8.6	-	-	-	-
		Grade 3	2	0.5	-	-	-	-
HIB form 2	Any	-	-	43	10.5	-	-	
	Grade 3	-	-	0	0.0	-	-	
Redness	DTPa-HBV/Hib	Any	-	-	-	-	143	34.0
		>20 mm	-	-	-	-	6	1.4
	DTPa-HBV	Any	127	29.5	126	30.8	-	-
		>20 mm	5	1.2	3	0.7	-	-
	HIB form 1	Any	76	17.6	-	-	-	-
		>20 mm	2	0.5	-	-	-	-
HIB form 2	Any	-	-	90	22.0	-	-	
	>20 mm	-	-	1	0.2	-	-	
Swelling	DTPa-HBV/Hib	Any	-	-	-	-	103	24.5
		>20 mm	-	-	-	-	19	4.5
	DTPa-HBV	Any	111	25.8	93	22.7	-	-
		>20 mm	15	3.5	10	2.4	-	-
	HIB form 1	Any	56	13.0	-	-	-	-
		>20 mm	6	1.4	-	-	-	-
HIB form 2	Any	-	-	59	14.4	-	-	
	>20 mm	-	-	5	1.2	-	-	

N = total number of symptom sheets returned

n = number of symptom sheets reporting a particular symptom

Any = occurrence of any solicited general symptom regardless of their intensity grade

Grade 3 Pain = cried when the limb was moved

Secondary Outcome Variable(s):

Incidence of each solicited general symptom reported during the 4-day (Day 0-3) post-vaccination period including those graded with maximum intensity and considered related to vaccination (ATP cohort for safety).

		DTPa-HBV+ Hib F1 Group N = 431		DTPa-HBV+ Hib F2 Group N = 409		DTPa-HBV/Hib Group N = 420	
		n	%	n	%	n	%
Diarrhoea	Any	42	9.7	58	14.2	48	11.4
	Grade 3	2	0.5	3	0.7	0	0.0
	Related	13	3.0	18	4.4	16	3.8
Fever	≥37.5°C	64	14.8	69	16.9	58	13.8
	≥39.1°C	2	0.5	3	0.7	4	1.0
	Related	38	8.8	41	10.0	33	7.9
Fussiness	Any	97	22.5	96	23.5	91	21.7
	Grade 3	5	1.2	7	1.7	11	2.6
	Related	66	15.3	65	15.9	74	17.6
Loss of appetite	Any	88	20.4	62	15.2	52	12.4
	Grade 3	3	0.7	3	0.7	4	1.0
	Related	55	12.8	32	7.8	33	7.9
Restlessness	Any	108	25.1	102	24.9	122	29.0
	Grade 3	7	1.6	7	1.7	13	3.1
	Related	76	17.6	72	17.6	87	20.7
Sleeping more than usual	Any	136	31.6	109	26.7	98	23.3
	Grade 3	8	1.9	4	1.0	3	0.7
	Related	98	22.7	79	19.3	73	17.4
Unusual crying	Any	108	25.1	98	24.0	104	24.8
	Grade 3	5	1.2	7	1.7	17	4.0
	Related	84	19.5	73	17.8	82	19.5
Vomiting	Any	53	12.3	42	10.3	39	9.3
	Grade 3	4	0.9	0	0.0	4	1.0
	Related	27	6.3	23	5.6	17	4.0

N = total number of symptom sheets returned

n = number of symptom sheets reporting a particular symptom

Any = symptoms reported over the 4-day follow-up period irrespective of their intensity

Related = considered by the investigator to be probably, or suspected of being, related to vaccination.

Grade 3 Fussiness = persistent crying that could not be comforted

Grade 3 Symptom = symptom that prevented normal activity

Safety Results: Number (%) of subjects with adverse events (ATP cohort for safety).

Most frequent adverse events On-Therapy (occurring within Day 0-30 following vaccination)	DTPa-HBV+ Hib F1 Group N = 144	DTPa-HBV+ Hib F2 Group N = 137	DTPa-HBV/Hib Group N = 142
Subjects with any AE(s), n (%)	52 (36.1)	37 (27.0)	47 (33.1)
Subjects with grade 3 AE(s), n (%)	3 (2.1)	4 (2.9)	1 (0.7)
Subjects with related AE(s), n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Otitis media	14 (9.7)	9 (6.6)	9 (6.3)
Bronchitis	13 (9.0)	-	8 (5.6)
Cough	7 (4.9)	5 (3.6)	6 (4.2)

Upper respiratory tract infection	4 (2.8)	5 (3.6)	7 (4.9)
Rhinitis	9 (6.2)	5 (3.4)	3 (2.1)
Eczema	7 (4.9)	3 (2.2)	4 (2.8)
Pyrexia	8 (5.6)	-	3 (2.1)
Conjunctivitis	2 (1.4)	4 (2.9)	2 (1.4)
Pharyngitis	3 (2.1)	4 (2.9)	-
Viral infection	2 (1.4)	3 (2.2)	2 (1.4)
Gastroenteritis	-	3 (2.2)	2 (1.4)
Fungal infection	-	3 (2.2)	-
Injection site reaction	-	-	3 (2.1)
Injection site mass	-	-	3 (2.1)
Croup infectious	2 (1.4)	-	-
Diarrhoea	-	-	2 (1.4)
Herpes zoster	-	-	2 (1.4)
Vomiting	-	-	2 (1.4)

- : Adverse event absent or not meeting the selected rule(s)

More than 30 subjects per treatment group and <= 3 groups: the most frequent 10 events in each group

Safety Results: Number (%) of subjects with serious adverse events (Total Vaccinated Cohort)

Serious adverse event, n (%) [n considered by the investigator to be related to study medication]

All SAEs	DTPa-HBV+ Hib F1 Group N = 159	DTPa-HBV+ Hib F2 Group N = 155	DTPa-HBV/Hib Group N = 157
Subjects with any SAE(s), n (%) [n related]	1 (0.6) [0]	1 (0.6) [0]	2 (1.3) [0]
Bronchiolitis	0 (0.0) [0]	1 (0.6) [0]	1 (0.6) [0]
Kawazaki	0 (0.0) [0]	0 (0.0) [0]	1 (0.6) [0]
Bronchitis	1 (0.6) [0]	0 (0.0) [0]	0 (0.0) [0]
Fatal SAEs	DTPa-HBV+ Hib F1 Group	DTPa-HBV+ Hib F2 Group	DTPa-HBV/Hib Group
Subjects with fatal SAE(s), n (%) [n related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Conclusion: One month after the third vaccine dose, at least 98.1% and 86% of subjects in each group had anti-PRP antibody concentrations ≥ 0.15 g /mL and 1 μ g/mL, respectively. At least one unsolicited adverse event was reported by 52 (36.1%), 37 (27.0%) and 47 (33.1%) subjects in the DTPa-HBV+ Hib F1, DTPa-HBV+ Hib F2 and DTPa-HBV/Hib groups, respectively, during the 30 day follow-up period after vaccination. SAEs were reported for 1 (0.6%), 1 (0.6%) and 2 (1.3%) subjects in the DTPa-HBV+ Hib F1, DTPa-HBV+ Hib F2 and DTPa-HBV/Hib groups, respectively; none were considered by the investigators to have a causal relationship with the study vaccination. No fatal SAEs were reported during the study.

Publications: None

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