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Study No.: 347414/036	
Title: A phase-III, open, controlled study to assess the safety and immunogenicity of four different formulations of GlaxoSmithKline Biologicals' (GSK Biologicals) investigational vaccination regimen when administered as a booster to healthy infants, 12 to 16 months old, previously vaccinated in infancy in a primary study.	
Rationale: The purpose of the present study was to assess the safety and immunogenicity of a booster dose of 4 formulations of an investigational vaccination regimen when administered to children between 12 and 16 months of age.	
Phase: III	
Study Period: 12 February 2002 to 25 July 2002.	
Study Design: Open, randomised, controlled, multicentric with 5 parallel groups (1:1:1:1:1) Data from the group receiving a currently registered vaccine are presented. Data from the investigational vaccination regimen, which is not yet approved or marketed, are not reported at this time.	
Centres: Several centres in Lithuania.	
Indication: Booster vaccination against <i>Haemophilus influenzae</i> type b at 12-16 months of age.	
Treatment: The 5 treatment groups were as follows: <ul style="list-style-type: none"> • 4 groups received 4 different formulations of the investigational vaccination regimen • 1 control group received a commercially available vaccine against Haemophilus influenzae type B (Hib). Vaccines were administered by intramuscular injection in the left thigh.	
Objectives: To assess the immune response induced in infants by a booster dose of the 4 formulations of an investigational vaccination regimen.	
Primary Outcome/Efficacy Variable: Not Applicable.	
Secondary Outcome/Efficacy Variable(s): <i>Only outcome variables related to the commercially available vaccines are presented</i> <ul style="list-style-type: none"> • Occurrence of each solicited local and general symptom within 8 days (Day 0-7) after the administration of the booster dose, • Occurrence of unsolicited adverse events (AEs) within 31 days (Day 0-30) after the administration of the booster dose, • Occurrence of any serious adverse events (SAEs) within 31 days (Day 0-30) after the administration of the booster dose, • Occurrence of any SAEs between Visit 4 of the primary study and Visit 1 of this booster study. 	
Statistical Methods: The analyses were performed on the Total Vaccinated cohort. - The Total Vaccinated cohort included all subjects who received the booster vaccine dose. <i>Analysis of safety:</i> The analysis of safety was performed on the Total Vaccinated cohort. For the solicited local and general symptoms, the percentage of subjects with the symptom reported during the 8-day (Day 0-7) follow-up period was summarized with exact 95% CI. The percentage of subjects with unsolicited AEs within 31 days (Day 0-30) following the booster dose administration was tabulated according to the World Health Organization (WHO) preferred term. The occurrence of SAEs was tabulated according to the Medical Dictionary for Regulatory Activities (MedDRA) preferred term since the last dose of the primary vaccination course and within 31 days (Day 0-30) after the administration of the booster vaccine dose.	
Study Population: A male or female infant between, and including, 12 and 16 months of age at the time of booster vaccination. Subjects had received at least one dose of an investigational vaccination regimen or a commercially available vaccine against Hib in the primary study. Subjects were free of obvious health problems as established by medical history and clinical examination before entering into the study. Written informed consent was obtained from a parent or guardian of the subject prior to inclusion into the booster study.	
Number of subjects	Control group
Planned, N	80
Randomised, N (Total Vaccinated Cohort)	70
Completed, n (%)	70 (100)
Total Number Subjects Withdrawn, n (%)	0 (0.0)

Withdrawn due to Adverse Events, n (%)				0 (0.0)	
Withdrawn due to Lack of Efficacy, n (%)				Not applicable	
Withdrawn for other reasons, n (%)				0 (0.0)	
Demographics				Control group	
N (Total Vaccinated Cohort)				70	
Females:Males				40:30	
Mean Age, months (SD)				14.1 (1.02)	
White/Caucasian, n (%)				69 (98.6)	
Primary Efficacy Results: Not Applicable					
Secondary Outcome/Efficacy Variable(s): Number and percentage of subjects with solicited local symptoms during the 8-day (Day 0-7) follow-up period after the booster vaccination (Total Vaccinated cohort)					
Symptom	Intensity	n	%	95% CI	
				LL	UL
N = 70					
Pain	Any	7	10.0	4.1	19.5
	Grade 3	0	0.0	0.0	5.1
Redness	Any	18	25.7	16.0	37.6
	> 30 mm	1	1.4	0.0	7.7
Swelling	Any	4	5.7	1.6	14.0
	> 30 mm	0	0.0	0.0	5.1
N: number of subjects with a sheet completed n (%): number (percentage) of subjects for whom a specific symptom was reported Any: incidence of a particular symptom regardless of grade Grade 3 Pain: cried when limb was moved/spontaneously painful 95% CI: exact 95% confidence interval; LL: lower limit, UL: upper limit					
Secondary Outcome/Efficacy Variable(s): Number and percentage of subjects with solicited general symptoms during the 8-day (Day 0-7) follow-up period after the booster vaccination (Total Vaccinated cohort)					
Symptom	Intensity/ Relationship	n	%	95% CI	
				LL	UL
N = 70					
Drowsiness	Any	12	17.1	9.2	28.0
	Grade 3	1	1.4	0.0	7.7
	Related	10	14.3	7.1	24.7
Irritability	Any	11	15.7	8.1	26.4
	Grade 3	0	0.0	0.0	5.1
	Related	10	14.3	7.1	24.7
Loss of appetite	Any	11	15.7	8.1	26.4
	Grade 3	1	1.4	0.0	7.7
	Related	10	14.3	7.1	24.7
Temperature (Rectal)	≥ 38.0°C	5	7.1	2.4	15.9
	> 40.0°C	0	0.0	0.0	5.1
	Related	4	5.7	1.6	14.0
N: number of subjects with a symptom sheet completed n (%): number (percentage) of subjects for whom a specific symptom was reported Any: incidence of a particular symptom regardless of grade and relationship to vaccination Related: symptoms considered by the investigator to have a causal relationship to study vaccination Grade 3 Drowsiness: drowsiness which prevented normal everyday activities Grade 3 Irritability: crying that could not be comforted/prevented normal everyday activities Grade 3 Loss of appetite: not eating at all 95% CI: exact 95% confidence interval; LL: lower limit, UL: upper limit					
Safety Results: Number (%) of subjects with unsolicited AEs (Total Vaccinated cohort)					
Most Frequent AEs - On-Therapy (occurring within Day 0-30 following vaccination)				Control group N = 70	

Subjects with any AE(s), n (%)	18 (25.7)
Pharyngitis	5 (7.1)
Upper respiratory tract infection	4 (5.7)
Bronchitis	2 (2.9)
Otitis media	2 (2.9)
Anemia	1 (1.4)
Dermatitis	1 (1.4)
Dyspepsia	1 (1.4)
Infection viral	1 (1.4)
Injury	1 (1.4)
Malformation foot	1 (1.4)
Rash	1 (1.4)
Rhinitis	1 (1.4)
Stomatitis	1 (1.4)
Tooth ache	1 (1.4)
Safety Results: Number (%) of subjects with SAEs up to Day 30 after the administration of the booster dose (Total Vaccinated cohort)	
SAE, n (%) [n considered by the investigator to be related to study medication]	
All SAEs	Control group N = 70
Subjects with any SAE(s), n (%) [n related]	0 (0.0) [0]
Fatal SAEs	Control group N = 70
Subjects with fatal SAE(s), n (%) [n related]	0 (0.0) [0]
Safety Results: Number (%) of subjects with SAEs* between Visit 4 of the primary study (347414/023) and Visit 1 of this booster study (Total Vaccinated cohort)	
SAE, n (%) [n considered by the investigator to be related to study medication]	
* the data were not available for the writing of the CTR	

Conclusion: The most frequently reported solicited local symptom was redness (25.7%). Drowsiness was the most frequently reported solicited general symptom (17.1%). At least one unsolicited AE was reported for 25.7% of the subjects. No SAEs were reported during the study period.

Publications: No Publication

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