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Study No.: 103954 (Hib-MenC-TT-011)
Title: A phase III, open (partially double-blind), randomized, controlled, multicenter study to evaluate the safety, reactogenicity and immunogenicity of a booster dose of GlaxoSmithKline (GSK) Biologicals' <i>Haemophilus influenzae</i> type b - meningococcal serogroup C (Hib-MenC) conjugate vaccine given concomitantly with GSK Biologicals' measles, mumps and rubella (MMR) vaccine (Priorix) [™] versus Hib-MenC only and MMR only, in toddlers aged 13–14 months who have been primed in infancy with three doses of Hib (given as part of a combined DTPa –containing vaccine) and meningococcal serogroup C CRM197 (MenC-CRM ₁₉₇) conjugate vaccines. Hib-MenC (<i>Menitorix</i>): GlaxoSmithKline (GSK) Biologicals' <i>Haemophilus influenzae</i> type b meningococcal serogroup C tetanus toxoid conjugate vaccine. Priorix [™] (MMR): GSK Biologicals' combined measles, mumps and rubella vaccine. DTPa: licensed diphtheria, tetanus, acellular pertussis vaccine. Hib: <i>Haemophilus influenzae</i> type b vaccine.
Rationale: The purpose of this study was to evaluate the safety and immunogenicity of a booster dose of Hib-MenC conjugate vaccine given concomitantly with MMR vaccine versus Hib-MenC only and MMR only, in toddlers aged 13–14 months who have been primed in infancy with 3 doses of Hib (given as part of a combined DTPa containing vaccine) and MenC-CRM ₁₉₇ conjugate vaccine.
Phase: III
Study Period: 22 March 2005 to 23 September 2005
Study Design: Open (but double-blind with respect to the 3 Hib-MenC vaccine lots used in this study), randomized (1:1:1 ratio), multi-centre, controlled, self-contained study with 3 parallel groups.
Centres: 19 centres in Spain.
Indication: Booster vaccination against <i>Haemophilus influenzae</i> type b and meningococcal serogroup C diseases, and vaccination against measles, mumps and rubella in healthy toddlers aged 13-14 months, primed with 3 doses of Hib (given as part of a combined DTPa containing vaccine) and MenC-CRM ₁₉₇ vaccines.
Treatment: The 3 study groups received a single booster dose at the age of 13 -14 months as follows: <ul style="list-style-type: none"> • Hib-MenC + MMR Group: subjects received Hib-MenC* vaccine concomitantly with MMR vaccine. • Hib-MenC Group: subjects received Hib-MenC* vaccine. • MMR Group: subjects received MMR vaccine. *Three different lots of Hib-MenC vaccine were used in this study, subjects in each treatment group receiving Hib-MenC were equally randomized [1:1:1] to receive 1 of the 3 lots. Hib-MenC vaccine was administered intramuscularly in the left upper thigh; MMR vaccine was administered subcutaneously in the right upper thigh.
Objectives: To evaluate the safety of a booster dose of the Hib-MenC conjugate vaccine when co-administered with MMR vaccine to healthy toddlers aged 13 – 14 months in terms of the occurrence of any grade 3 solicited symptoms within 4 days (Day 0 – 3) after the booster vaccination.
Primary Outcome/Efficacy Variable: The occurrence of any grade 3 solicited symptoms within 4 days (Day 0-3) after the booster vaccination.
Secondary Outcome/Efficacy Variable(s): Immunogenicity: <i>Just prior to and 42 days after vaccination, in all evaluable subjects having received Hib-MenC:</i> <ul style="list-style-type: none"> • Serum bactericidal assay/activity against <i>Neisseria meningitidis</i> serogroup C (SBA-MenC) titres ≥ 1:8 (seroprotection), ≥ 1:128, and titres. • Anti-PRP concentration ≥ 0.15 µg/mL, ≥ 1.0 µg/mL and concentrations.

- Anti-PSC concentration $\geq 0.30 \mu\text{g/mL}$ (seropositivity), $\geq 2.0 \mu\text{g/mL}$, and concentrations.
- Just prior to and 42 days after vaccination, in all evaluable subjects having received MMR vaccine :*
- Anti-measles antibody concentration $\geq 150 \text{ mIU/mL}$ and concentrations.
 - Anti-mumps antibody concentration $\geq 231 \text{ U/mL}$ and concentrations.
 - Anti-rubella antibody concentration $\geq 4 \text{ IU/mL}$ and concentrations.
- 42 days after vaccination, in all evaluable subjects having received MMR vaccine :*
- Anti-measles, anti-mumps, anti-rubella seroconversion, defined as the appearance of antibodies (i.e. seropositivity) in subjects initially seronegative.

Safety :

- Occurrence of solicited local and general symptoms occurring within 4 days (Day 03) after the vaccination.
- Occurrence of unsolicited non-serious adverse events (AEs) occurring within 43 days (Day 0-42) after the vaccination.
- Occurrence of serious adverse events (SAEs) occurring throughout the study.
- Occurrence of MMR-specific general symptoms (fever, rash / exanthem, parotid /salivary gland swelling, any suspected signs of meningism (including febrile convulsions)) within 43 days (Day 0-42) after the vaccination, for all subjects, including those who did not receive the MMR vaccine.

Statistical Methods:

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

The Total Vaccinated Cohort included all vaccinated subjects for whom data were available.

The ATP cohort for immunogenicity included all subjects who received the vaccine according to their random assignment, who had not received a vaccine not specified or forbidden in the protocol, who met all eligibility criteria as defined in the report and analysis plan, who complied with the procedures defined in the protocol and for whom assay results were available.

Analysis of immunogenicity

The analysis of immunogenicity was performed on the ATP cohort for immunogenicity.

For the 2 groups receiving the Hib-MenC booster, prior to and 42 days after booster vaccination: Seropositivity / seroprotection rates and percentage of subjects above proposed cut-off with exact 95% confidence intervals (95% CIs) and geometric mean antibody concentrations/titres (GMCs/GMTs) with 95% CIs for SBA-MenC, anti-PSC and anti-PRP.

For the 2 groups receiving the MMR vaccine, prior to and 42 days after vaccination: Seroconversion rates with exact 95% CIs and GMCs for subjects who were seronegative before vaccination with 95% CIs for anti-measles, anti-mumps and anti-rubella antibodies.

Analysis of safety

The analysis of safety was performed on the Total Vaccinated Cohort.

The percentage of subjects with each individual solicited local and general symptom during the 4-day (Day 0-3) follow-up period was tabulated with exact 95% CI. The same tabulation was performed for grade 3 symptoms and for solicited general symptoms with a reasonable possibility of being related to vaccination. The percentage of subjects with other MMR specific solicited symptoms during the 43-day (Day 0-42) follow-up period after the vaccination was also tabulated with exact 95% CI. The percentage of subjects with at least one unsolicited AE classified by the Medical Dictionary for Regulatory Activities (MedDRA) preferred terms and reported up to 43 days (Day 0-42) after vaccination was tabulated. The occurrence of serious adverse events throughout the entire study period was tabulated according to the MedDRA preferred term.

Study Population: A male or female subject between, and including, 13 and 14 months of age at the time of the vaccination, free of obvious health problems as established by medical history and clinical examination before entering into the study, who previously completed three-dose primary vaccination with a MenC-CRM₁₉₇ vaccine, and Hib (given as part of a combined DTPa-containing vaccine) according to routine primary vaccination schedule in Spain with a minimum interval of 6 months between the administration of a third primary vaccination dose and the study entry. Written informed consent was obtained from the parent or guardian of the subject prior to study entry.

Number of subjects	Hib-MenC + MMR	Hib-MenC Group	MMR Group
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	Group														
Planned, N	99														
Randomised, N (Total Vaccinated Cohort)	102														
Completed, n (%)	101 (99.0)														
Total Number Subjects Withdrawn, n (%)	1 (1.0)														
Withdrawn due to Adverse Events, n (%)	0 (0.0)														
Withdrawn due to Lack of Efficacy, n (%)	Not applicable														
Withdrawn for other reasons, n (%)	1 (1.0)														
Demographics	Hib-MenC + MMR Group			Hib-MenC Group			MMR Group								
N (Total Vaccinated Cohort)	102														
Females:Males	41:61														
Mean Age, months (SD)	13.4 (0.52)														
White/Caucasian, n (%)	97 (95.1)														
Primary Efficacy Results:															
Incidence and nature of grade 3 solicited symptoms reported during the 4-day (Day 0-3) post-vaccination period following the booster dose (Total vaccinated cohort)															
Group	Any symptom					General symptoms					Local symptoms				
	N	n	%	95% CI		N	n	%	95% CI		N	n	%	95% CI	
				LL	UL				LL	UL				LL	UL
Hib-MenC + MMR	102	9	8.8	4.1	16.1	102	2	2.0	0.2	6.9	102	7	6.9	2.8	13.6
Hib-MenC	104	3	2.9	0.6	8.2	104	0	0.0	0.0	3.5	104	3	2.9	0.6	8.2
MMR	91	2	2.2	0.3	7.7	91	2	2.2	0.3	7.7	91	0	0.0	0.0	4.0
N = number of subjects with an administered dose n (%) = number (percentage) of subjects presenting at least one type of solicited symptom 95% CI = exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit															
Secondary Outcome Variable(s):															
Percentage of subjects with titres $\geq 1:8$ or $1:128$ and GMTs for SBA-MenC antibodies prior to and 42 days after booster vaccination (ATP cohort for immunogenicity)															
Group	Timing	N	$\geq 1:8$				$\geq 1:128$				GMT				
			n	%	95% CI		n	%	95% CI		Value	95% CI			
					LL	UL			LL	UL		LL	UL		
Hib-MenC + MMR	PRE	93	82	88.2	79.8	93.9	43	46.2	35.8	56.9	103.8	74.2	145.1		
	PI(D42)	95	94	98.9	94.3	100	85	89.5	81.5	94.8	670.2	497.9	902.1		
Hib-MenC	PRE	94	80	85.1	76.3	91.6	53	56.4	45.8	66.6	107.1	74.1	154.7		
	PI(D42)	95	94	98.9	94.3	100	88	92.6	85.4	97.0	685.0	527.0	890.4		
GMT = geometric mean titre calculated on all subjects N = number of subjects with available results n (%) = number (percentage) of subjects with antibody titre within the specified range 95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit PRE = pre-booster dose PI(D42) = post-booster dose (Day 42)															
Secondary Outcome Variable(s):															
Seroprotection rates and GMCs for anti-PRP antibodies prior to and 42 days after booster															

vaccination (ATP cohort for immunogenicity)

Group	Timing	N	≥ 0.15 µg/mL				≥ 1 µg/mL				GMC (µg/mL)		
			n	%	95% CI		n	%	95% CI		Value	95% CI	
					LL	UL			LL	UL		LL	UL
Hib-MenC + MMR	PRE	96	85	88.5	80.4	94.1	32	33.3	24.0	43.7	0.632	0.483	0.826
	PI(D42)	95	95	100	96.2	100	93	97.9	92.6	99.7	37.169	28.334	48.760
Hib-MenC	PRE	96	78	81.3	72.0	88.5	29	30.2	21.3	40.4	0.580	0.433	0.777
	PI(D42)	96	96	100	96.2	100	95	99.0	94.3	100	30.266	23.550	38.897

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n (%) = number (percentage) of subjects with antibody concentration within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PRE = pre-booster dose

PI(D42) = post-booster dose (Day 42)

Secondary Outcome Variable(s):

Seropositivity rates and GMCs for anti-PSC antibodies prior to and 42 days after booster vaccination (ATP cohort for immunogenicity)

Group	Timing	N	≥ 0.3 µg/mL				≥ 2 µg/mL				GMC (µg/mL)		
			n	%	95% CI		n	%	95% CI		Value	95% CI	
					LL	UL			LL	UL		LL	UL
Hib-MenC + MMR	PRE	96	87	90.6	82.9	95.6	22	22.9	15.0	32.6	1.02	0.81	1.27
	PI(D42)	96	96	100	96.2	100	69	71.9	61.8	80.6	3.33	2.75	4.05
Hib-MenC	PRE	94	89	94.7	88.0	98.3	27	28.7	19.9	39.0	1.14	0.94	1.37
	PI(D42)	96	96	100	96.2	100	73	76.0	66.3	84.2	3.36	2.82	4.00

GMC = geometric mean antibody concentration calculated on all subjects

N = number of subjects with available results

n (%) = number (percentage) of subjects with antibody concentration within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

PRE = pre-booster dose

PI(D42) = post-booster dose (Day 42)

Secondary Outcome Variable (s):

Seroconversion rates and GMCs for anti-measles antibodies 42 days after vaccination (ATP cohort for immunogenicity)

Group	N	≥ 150 mIU/mL				GMC (mIU/mL)			
		n	%	95% CI		Value	95% CI		
				LL	UL		LL	UL	
Hib-MenC + MMR	96	95	99.0	94.3	100	2706.6	2241.9	3267.7	
MMR	78	75	96.2	89.2	99.2	2829.4	2222.2	3602.5	

N = number of subjects with available results at 42 days after vaccination and who were seronegative before vaccination

n (%) = number (percentage) of subjects with antibody concentration within the specified range

95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Secondary Outcome Variable (s):

Seroconversion rates and GMCs for anti-mumps antibodies 42 days after vaccination (ATP cohort for immunogenicity)

Group	N	≥ 231 U/mL				GMC (U/mL)			
		n	%	95% CI		Value	95% CI		
				LL	UL		LL	UL	
Hib-MenC + MMR	95	89	93.7	86.8	97.6	1041.9	859.0	1263.7	

MMR	79	74	93.7	85.8	97.9	1232.3	1003.7	1513.0								
<p>N = number of subjects with available results at 42 days after vaccination and who were seronegative before vaccination n (%) = number (percentage) of subjects with antibody concentration within the specified range 95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit</p>																
Secondary Outcome Variable (s):																
Seroconversion rates and GMCs for anti-rubella antibodies 42 days after vaccination (ATP cohort for immunogenicity)																
Group	N	≥ 4 IU/mL				GMC (IU/mL)										
		n	%	95% CI		Value	95% CI									
				LL	UL		LL	UL								
Hib-MenC + MMR	95	95	100	96.2	100	102.3	84.7	123.6								
MMR	78	78	100	95.4	100	117.6	98.7	140.0								
<p>GMC = geometric mean antibody concentration calculated on all subjects who were seronegative (< 4 IU/ml) before vaccination N = number of subjects with available results at 42 days after vaccination and who were seronegative before vaccination n (%) = number (percentage) of subjects with antibody concentration within the specified range 95% CI = 95% confidence interval; LL = Lower Limit, UL = Upper Limit</p>																
Secondary Outcome Variable (s):																
Incidence of solicited local symptoms reported during the 4-day (Day 0-3) post-vaccination period (Total Vaccinated Cohort)																
Symptom	Intensity	Hib-MenC + MMR Group					Hib-MenC Group					MMR Group				
		N	n	%	95% CI		N	n	%	95% CI		N	n	%	95% CI	
					LL	UL				LL	UL				LL	UL
Pain	Any	102	21	20.6	13.2	29.7	104	19	18.3	11.4	27.1	91	11	12.1	6.2	20.6
	Grade 3	102	1	1.0	0.0	5.3	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
Redness	Any	102	26	25.5	17.4	35.1	104	22	21.2	13.8	30.3	91	10	11.0	5.4	19.3
	> 30 mm	102	6	5.9	2.2	12.4	104	2	1.9	0.2	6.8	91	0	0.0	0.0	4.0
Swelling	Any	102	13	12.7	7.0	20.8	104	8	7.7	3.4	14.6	91	1	1.1	0.0	6.0
	> 30 mm	102	2	2.0	0.2	6.9	104	1	1.0	0.0	5.2	91	0	0.0	0.0	4.0
<p>N = number of subjects with an administered dose n (%) = number (percentage) of subjects for whom the symptom was reported at least once 95% CI = Exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit Any = any solicited local symptom regardless of intensity grade Grade 3 pain = crying when limb was moved/spontaneously painful</p>																
Secondary Outcome Variable (s):																
Incidence of solicited general symptoms reported during the 4-day (Day 0-3) post-vaccination period (Total Vaccinated Cohort)																
Symptom	Intensity/Relationship	Hib-MenC + MMR Group					Hib-MenC Group					MMR Group				
		N	n	%	95% CI		N	n	%	95% CI		N	n	%	95% CI	
					LL	UL				LL	UL				LL	UL
Drowsiness	Any	102	20	19.6	12.4	28.6	104	15	14.4	8.3	22.7	91	17	18.7	11.3	28.2
	Grade 3	102	0	0.0	0.0	3.6	104	0	0.0	0.0	3.5	91	1	1.1	0.0	6.0
	Related	102	13	12.7	7.0	20.8	104	8	7.7	3.4	14.6	91	6	6.6	2.5	13.8

Fever (Rectally)	≥ 38°C	102	13	12.7	7.0	20.8	104	22	21.2	13.8	30.3	91	15	16.5	9.5	25.7
	> 40°C	102	1	1.0	0.0	5.3	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
	Related	102	9	8.8	4.1	16.1	104	8	7.7	3.4	14.6	91	7	7.7	3.1	15.2
Irritability	Any	102	25	24.5	16.5	34.0	104	22	21.2	13.8	30.3	91	30	33.0	23.5	43.6
	Grade 3	102	0	0.0	0.0	3.6	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
	Related	102	16	15.7	9.2	24.2	104	11	10.6	5.4	18.1	91	17	18.7	11.3	28.2
Loss of appetite	Any	102	20	19.6	12.4	28.6	104	17	16.3	9.8	24.9	91	22	24.2	15.8	34.3
	Grade 3	102	1	1.0	0.0	5.3	104	0	0.0	0.0	3.5	91	1	1.1	0.0	6.0
	Related	102	13	12.7	7.0	20.8	104	9	8.7	4.0	15.8	91	10	11.0	5.4	19.3

N = number of subjects with an administered dose

n (%) = number (percentage) of subjects for whom the symptom was reported at least once

95% CI = Exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Any = any solicited general symptom regardless of intensity grade or relationship

Grade 3 drowsiness = drowsiness that prevented normal activity

Grade 3 irritability = crying that could not be comforted

Grade 3 loss of appetite = not eating at all

Related = symptoms considered by the investigator to have a causal relationship to the study vaccination

Secondary Outcome Variable (s):

Incidence of MMR-specific solicited symptoms reported during the 43-day (Day 0-42) follow-up period following vaccination (Total Vaccinated Cohort)

Symptom	Type	Hib-MenC + MMR Group					Hib-MenC Group					MMR Group				
		N	n	%	95 % CI		N	n	%	95 % CI		N	n	%	95 % CI	
					LL	UL				LL	UL				LL	UL
Fever (Rectally)	≥ 38.0°C	102	67	65.7	55.6	74.8	104	58	55.8	45.7	65.5	91	61	67.0	56.4	76.5
	> 40.0°C	102	4	3.9	1.1	9.7	104	1	1.0	0.0	5.2	91	4	4.4	1.2	10.9
	Related	102	30	29.4	20.8	39.3	104	11	10.6	5.4	18.1	91	28	30.8	21.5	41.3
Meningism	Any	102	0	0.0	0.0	3.6	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
	Grade 3	102	0	0.0	0.0	3.6	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
	Related	102	0	0.0	0.0	3.6	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
Parotid gland swelling	Any	102	0	0.0	0.0	3.6	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
	Grade 3	102	0	0.0	0.0	3.6	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
	Related	102	0	0.0	0.0	3.6	104	0	0.0	0.0	3.5	91	0	0.0	0.0	4.0
Rash	Any	102	15	14.7	8.5	23.1	104	13	12.5	6.8	20.4	91	10	11.0	5.4	19.3
	Grade 3	102	3	2.9	0.6	8.4	104	1	1.0	0.0	5.2	91	2	2.2	0.3	7.7
	Related	102	6	5.9	2.2	12.4	104	0	0.0	0.0	3.5	91	1	1.1	0.0	6.0

N = number of subjects with an administered dose

n (%) = number (percentage) of subjects for whom the symptom was reported at least once

95% C: Exact 95% confidence interval; LL = Lower Limit, UL = Upper Limit

Any:= any solicited general symptom regardless of intensity grade or relationship

Grade 3 parotid gland swelling = swelling with accompanying general symptoms

Grade 3 meningism: meningism that prevented normal, everyday activities

Grade 3 rash: >150 lesions
 Related: symptoms considered by the investigator to have a causal relationship to the study vaccination

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

Most frequent adverse events - On-Therapy (occurring within Day 0-42 following vaccination)	Hib-MenC + MMR Group N = 102	Hib-MenC Group N = 104	MMR Group N = 91
Subjects with any AE(s), n (%)	63 (61.8)	56 (53.8)	57 (62.6)
Upper respiratory tract infection	21 (20.6)	20 (19.2)	24 (26.4)
Gastroenteritis	6 (5.9)	10 (9.6)	6 (6.6)
Toothache	7 (6.9)	3 (2.9)	5 (5.5)
Pharyngitis	2 (2.0)	9 (8.7)	3 (3.3)
Conjunctivitis	4 (3.9)	5 (4.8)	4 (4.4)
Diarrhoea	6 (5.9)	4 (3.8)	2 (2.2)
Viral infection	5 (4.9)	2 (1.9)	5 (5.5)
Vomiting	4 (3.9)	7 (6.7)	1 (1.1)
Bronchitis	5 (4.9)	1 (1.0)	3 (3.3)
Laryngitis	3 (2.9)	1 (1.0)	5 (5.5)
Tonsillitis	4 (3.9)	2 (1.9)	3 (3.3)
Cough	1 (1.0)	5 (4.8)	0 (0.0)
Irritability	3 (2.9)	2 (1.9)	1 (1.1)
Pharyngotonsillitis	3 (2.9)	1 (1.0)	2 (2.2)
Acute tonsillitis	1 (1.0)	2 (1.9)	2 (2.2)
Otitis media	3 (2.9)	2 (1.9)	0 (0.0)
Otitis media acute	1 (1.0)	4 (3.8)	0 (0.0)
Arthropod bite	0 (0.0)	1 (1.0)	3 (3.3)
Ear infection	1 (1.0)	2 (1.9)	1 (1.1)
Rhinorrhoea	0 (0.0)	2 (1.9)	1 (1.1)

Safety Results: Number (%) of subjects with Serious Adverse Events (SAEs)

All SAEs	Hib-MenC + MMR Group N = 102	Hib-MenC Group N = 104	MMR Group N = 91
Subjects with any SAE(s), n (%) [n related]	1 (1.0) [0]	1 (1.0) [0]	1 (1.1) [0]
Burn oesophageal	0 (0.0) [0]	1 (1.0) [0]	0 (0.0) [0]
Mastoiditis	1 (1.0) [0]	0 (0.0) [0]	0 (0.0) [0]
Perianal abscess	0 (0.0) [0]	0 (0.0) [0]	1 (1.1) [0]
Thermal burn	0 (0.0) [0]	1 (1.0) [0]	0 (0.0) [0]
Fatal SAEs	Hib-MenC + MMR Group N = 102	Hib-MenC Group N = 104	MMR Group N = 91
Subjects with fatal SAE(s), n (%) [n related]	0 (0.0) [0]	0 (0.0) [0]	0 (0.0) [0]

Conclusion: Within 4 days after the vaccination, Grade 3 solicited symptoms (either general or local) were reported for 9 (8.8%), 3 (2.9%) and 2 (2.2%) of the subjects in the Hib-MenC + MMR, the Hib-MenC and the MMR group, respectively. Pain and redness were the most frequently reported solicited local symptoms while irritability was the most frequently reported solicited general symptoms in all groups. After the booster dose, 98.9% of subjects of the Hib-MenC + MMR and Hib-MenC group had SBA-MenC antibody titres $\geq 1:8$. At the same time point, all subjects had anti-PRP and anti-PSC antibody concentrations \geq specified cut-off values. Fever was the most frequently reported MMR-specific solicited general symptom. In the 2 groups vaccinated with MMR, at least 96.2%, 93.7% and 100% were protected against measles, mumps and rubella, respectively. At least one AE was

reported for 63 (61.8%), 56 (53.8%), and 57 (62.6%) subjects of the Hib-MenC + MMR, the Hib-MenC and the MMR groups, respectively. During the whole study course, one SAE was reported in each of the 3 study groups. These SAEs were considered by the investigators not to be related to the study vaccinations. No fatal SAEs were reported.

Publications: Carmona et al (2006) Immunogenicity, safety and reactogenicity of a booster dose of a Heamophilus influenzae type b and Neisseria meningitidis serogroup C-tetanus toxoid conjugate (Hib-MenC-TT) vaccine co-administered with MMR (Measles-Mumps-rubella) vaccine. Poster presented at ESPID 2006.

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