



Clinical trial results:

A phase II, open, controlled, multicenter study to evaluate the long-term antibody persistence at 1, 3 and 5 years after the administration of a four dose vaccination series of Hib-MenCY-TT vaccine compared to ActHIB in subjects given a four dose vaccination series in study Hib-MenCY-TT-005/006.

Summary

EudraCT number	2012-004060-22
Trial protocol	Outside EU/EEA
Global end of trial date	23 August 2011

Results information

Result version number	v1 (current)
This version publication date	27 April 2016
First version publication date	12 July 2015

Trial information

Trial identification

Sponsor protocol code	107824/107826/107829
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00359983
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupport@gsk.com
Scientific contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupport@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	14 February 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	12 May 2011
Global end of trial reached?	Yes
Global end of trial date	23 August 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

- To evaluate the long-term antibody persistence induced by 4 doses of Hib-MenCY-TT as compared to 4 doses of ActHIB given at 2, 4, 6, and 12 to 15 months of age in terms of the percentage of subjects with antibody to anti-PRP $\geq 0.15 \mu\text{g/mL}$.
- To evaluate the long-term antibody persistence induced by 4 doses of Hib-MenCY-TT given at 2, 4, 6, and 12 to 15 months of age in terms of percentage of subjects with hSBA-MenC and hSBA-MenY titers $\geq 1:8$.
- To evaluate the long-term antibody persistence induced by 3 doses of ActHIB given at 2, 4, 6 months of age, and a single dose of Hib-MenCY-TT at 12 to 15 months of age in terms of the percentage of subjects with anti-PRP concentrations $0.15 \mu\text{g/mL}$, hSBA-MenC and hSBA-MenY titers $\geq 1:8$.

Note: The hSBA-MenC and hSBA-MenY endpoint of titers $\geq 1:8$ reflect the primary endpoint for the analysis of persistence years 3 and 5.

Protection of trial subjects:

All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines. Subjects were followed-up from the time the subject consents to participate in the study until she/he is discharged.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	14 April 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	6 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 181
Worldwide total number of subjects	181
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
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Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	181
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Period 1

Period 1 title	Year 1 Persistence Follow-up
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	MenHibrix 4-dose Group

Arm description:

Subjects between 22 to 36 months of age received in the primary study (NCT00129129) 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.

Arm type	Experimental
Investigational medicinal product name	MenHibrix
Investigational medicinal product code	
Other name	Hib-MenCY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar

Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 intramuscular doses of Pediarix co-administered with MenHibrix

Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 intramuscular doses, 3 co-administered with MenHibrix and Pediarix and 1 dose co-administered with MenHibrix .

Arm title	ActHIB 4-dose group
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Arm description:

Subjects between 22 to 36 months of age received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a 4th dose of ActHIB co-administered with Prevnar. No vaccines were administered during this long-term persistence study.

Arm type	Active comparator
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Investigational medicinal product name	ActHIB
Investigational medicinal product code	
Other name	Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of ActHIB co-administered with Pediarix and Prevnar, administered intramuscularly.

Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 intramuscular doses of Pediarix co-administered with ActHIB and Prevnar

Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses administered intramuscularly, 3 co-administered with Pediarix and ActHIB and 1 co-administered with ActHIB.

Arm title	ActHIB 3-dose + MenHibrix 4th-dose group
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Arm description:

Subjects between 22 to 36 months of age received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.

Arm type	Experimental
Investigational medicinal product name	ActHIB
Investigational medicinal product code	
Other name	Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of ActHIB co-administered with Pediarix and Prevnar, administered intramuscularly.

Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of Pediarix co-administered with ActHIB and Prevnar

Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly and co-administered with ActHIB and Pediarix and a dose co-administered with MenHibrix

Investigational medicinal product name	MenHibrix
Investigational medicinal product code	
Other name	Hib-MenCY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose administered intramuscularly and co-administered with Prevnar.

Number of subjects in period 1	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group
Started	138	70	62
Completed	138	70	62

Period 2

Period 2 title	Year 3 Persistence Follow-up
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	MenHibrix 4-dose group

Arm description:

Subjects between 44 to 60 months of age received in the primary study (NCT00129129) 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.

Arm type	Experimental
Investigational medicinal product name	MenHibrix
Investigational medicinal product code	
Other name	Hib-MenCY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar

Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly and co-administered with MenHibrix and Prevnar

Investigational medicinal product name	Pprevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 intramuscular doses, 3 doses co-administered with Pediarix and MenHibrix, and a dose co-administered with MenHibrix	
Arm title	ActHIB 4-dose group
Arm description:	
Subjects between 44 to 60 months of age received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Pprevnar and a 4th dose of ActHIB co-administered with Pprevnar. No vaccines were administered during this long-term persistence study.	
Arm type	Active comparator
Investigational medicinal product name	ActHIB
Investigational medicinal product code	
Other name	Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received 3 doses of ActHIB co-administered with Pediarix and Pprevnar	
Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
3 doses administered intramuscularly and co-administered with Pprevnar and ActHIB	
Investigational medicinal product name	Pprevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 intramuscular doses, 3 co-administered with ActHIB and Pediarix, and 1 co-administered with ActHIB	
Arm title	ActHIB 3-dose + MenHibrix 4th-dose group
Arm description:	
Subjects between 44 to 60 months of age received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Pprevnar and a dose of MenHibrix co-administered with Pprevnar. No vaccines were administered during this long-term persistence study.	
Arm type	Experimental
Investigational medicinal product name	ActHIB
Investigational medicinal product code	
Other name	Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received 3 doses of ActHIB co-administered with Pediarix and Pprevnar	
Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:	
3 doses of Pediarix co-administered with ActHIB and Prevnar	
Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 intramuscular doses, 3 doses co-administered with Pediarix and ActHIB and 1 dose co-administered with MenHibrix	
Investigational medicinal product name	MenHibrix
Investigational medicinal product code	
Other name	Hib-MenCY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 dose of MenHibrix co-administered with Prevnar	

Number of subjects in period 2 ^[1]	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group
Started	103	47	51
Completed	103	47	51

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up study. Actual enrolment differed depending on the rate of return for the follow-up study, so not all enrolled subjects came to each visit.

Period 3

Period 3 title	Year 5 Persistence Follow-up
Is this the baseline period?	Yes ^[2]
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	MenHibrix 4-dose group

Arm description:

Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.

Arm type	Experimental
Investigational medicinal product name	MenHibrix
Investigational medicinal product code	
Other name	Hib-MenCY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:	
Subjects received 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar vaccine	
Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
3 doses administered intramuscularly and co-administered with Prevnar and MenHibrix vaccine	
Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses administered intramuscularly, 3 doses co-administered with Pediarix and MenHibrix, and 1 dose co-administered with MenHibrix vaccine	
Arm title	ActHIB 4-dose group
Arm description:	
Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a 4th dose of ActHIB co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Arm type	Active comparator
Investigational medicinal product name	ActHIB
Investigational medicinal product code	
Other name	Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
Subjects received 3 doses of ActHIB co-administered with Pediarix and Prevnar vaccine	
Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
3 doses administered intramuscularly and co-administered with Prevnar and ActHIB	
Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use
Dosage and administration details:	
4 doses administered intramuscularly, 3 co-administered with Pediarix and ActHIB, and 1 co-administered with ActHIB	
Arm title	ActHIB 3-dose + MenHibrix 4th-dose group
Arm description:	
Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Arm type	Experimental

Investigational medicinal product name	ActHIB
Investigational medicinal product code	
Other name	Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received 3 doses of ActHIB co-administered with Pediarix and Prevnar

Investigational medicinal product name	Pediarix
Investigational medicinal product code	
Other name	DTPa-HBV-IPV
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses administered intramuscularly and co-administered with Prevnar and ActHIB vaccine

Investigational medicinal product name	Prevnar
Investigational medicinal product code	
Other name	7Pn
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

4 doses administered intramuscularly, 3 doses co-administered with Pediarix and ActHIB and 1 dose co-administered with MenHibrix vaccine

Investigational medicinal product name	MenHibrix
Investigational medicinal product code	
Other name	Hib-MenCY-TT
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose administered intramuscularly and co-administered with Prevnar

Notes:

[2] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up study. Actual enrolment differed depending on the rate of return for the follow-up study, so not all enrolled subjects came to each visit.

Number of subjects in period 3 ^[3]	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group
Started	95	44	42
Completed	95	44	42

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Subjects not returning for a specific visit were not withdrawn and could participate in the subsequent follow-up study. Actual enrolment differed depending on the rate of return for the follow-up study, so not all enrolled subjects came to each visit.

Baseline characteristics

Reporting groups

Reporting group title	MenHibrix 4-dose group
Reporting group description:	
Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	ActHIB 4-dose group
Reporting group description:	
Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a 4th dose of ActHIB co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	ActHIB 3-dose + MenHibrix 4th-dose group
Reporting group description:	
Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	

Reporting group values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group
Number of subjects	95	44	42
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: months			
arithmetic mean	71.9	72	71.9
standard deviation	± 1.37	± 1.62	± 1.49
Gender categorical Units: Subjects			
Female	43	22	19
Male	52	22	23

Reporting group values	Total		
Number of subjects	181		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		

Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: months			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	84		
Male	97		

End points

End points reporting groups

Reporting group title	MenHibrix 4-dose Group
Reporting group description: Subjects between 22 to 36 months of age received in the primary study (NCT00129129) 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	ActHIB 4-dose group
Reporting group description: Subjects between 22 to 36 months of age received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a 4th dose of ActHIB co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	ActHIB 3-dose + MenHibrix 4th-dose group
Reporting group description: Subjects between 22 to 36 months of age received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	MenHibrix 4-dose group
Reporting group description: Subjects between 44 to 60 months of age received in the primary study (NCT00129129) 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	ActHIB 4-dose group
Reporting group description: Subjects between 44 to 60 months of age received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a 4th dose of ActHIB co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	ActHIB 3-dose + MenHibrix 4th-dose group
Reporting group description: Subjects between 44 to 60 months of age received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	MenHibrix 4-dose group
Reporting group description: Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of MenHibrix co-administered with Pediarix and Prevnar and a 4th dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	ActHIB 4-dose group
Reporting group description: Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a 4th dose of ActHIB co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	
Reporting group title	ActHIB 3-dose + MenHibrix 4th-dose group
Reporting group description: Subjects aged 5 years post-dose 4 +/- 8 weeks received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Prevnar and a dose of MenHibrix co-administered with Prevnar. No vaccines were administered during this long-term persistence study.	

Primary: Number of Subjects With Anti- Polyribosylribitol Phosphate (Anti-PRP) Antibody Concentrations Greater Than or Equal to 0.15 Microgram Per Milliliter

End point title	Number of Subjects With Anti- Polyribosylribitol Phosphate (Anti-PRP) Antibody Concentrations Greater Than or Equal to 0.15 Microgram Per Milliliter ^[1]
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End point description:

End point type	Primary
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End point timeframe:

One year after the fourth dose vaccination.

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	51	47	
Units: Subjects				
Year 1, Post Fourth dose [N=109;51;47]	109	51	47	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Anti- Polyribosylribitol Phosphate (Anti-PRP) Antibody Concentrations Greater Than or Equal to 0.15 Microgram Per Milliliter

End point title	Number of Subjects With Anti- Polyribosylribitol Phosphate (Anti-PRP) Antibody Concentrations Greater Than or Equal to 0.15 Microgram Per Milliliter ^[2]
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End point description:

End point type	Primary
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End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	27	34	
Units: Subjects				
Year 3, Post Fourth dose [N=55;27;34]	55	27	34	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Anti- Polyribosylribitol Phosphate (Anti-PRP) Antibody Concentrations Greater Than or Equal to 0.15 Microgram Per Milliliter

End point title	Number of Subjects With Anti- Polyribosylribitol Phosphate (Anti-PRP) Antibody Concentrations Greater Than or Equal to 0.15 Microgram Per Milliliter ^[3]
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End point description:

End point type	Primary
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End point timeframe:

Five years after the fourth dose vaccination.

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	35	31	
Units: Subjects				
Year 5, Post Fourth dose [N=77;35;31]	77	35	31	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Neisseria Meningitidis Serogroup C (MenC) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA)

End point title	Number of Subjects With Neisseria Meningitidis Serogroup C (MenC) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA) ^[4]
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End point description:

End point type	Primary
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End point timeframe:

One year after the fourth dose vaccination.

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	19	14	
Units: Subjects				
Year 1, hSBA-MenC, Post Fourth dose [N=35;19;14]	33	1	14	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Neisseria Meningitidis Serogroup C (MenC) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA)

End point title	Number of Subjects With Neisseria Meningitidis Serogroup C (MenC) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA) ^[5]
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End point description:

End point type	Primary
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End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	10	14	
Units: Subjects				
Year 3, hSBA-MenC, Post Fourth dose [N=19;10;14]	19	0	12	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Neisseria Meningitidis Serogroup C (MenC) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA)

End point title	Number of Subjects With Neisseria Meningitidis Serogroup C (MenC) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA) ^[6]
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End point description:

End point type	Primary
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End point timeframe:

Five years after the fourth dose vaccination.

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	13	11	
Units: Subjects				
Year 5, hSBA-MenC, Post Fourth dose [N=24;13;11]	23	1	11	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Neisseria Meningitidis Serogroup Y (MenY) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA)

End point title	Number of Subjects With Neisseria Meningitidis Serogroup Y (MenY) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA) ^[7]
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End point description:

End point type	Primary
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End point timeframe:

One year after the fourth dose vaccination.

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	19	14	
Units: Subjects				
Year 1, hSBA-MenY, Post Fourth dose [N=35;19;14]	33	1	8	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Neisseria Meningitidis Serogroup Y (MenY) Antibody Titers Greater Than or Equal to 1:8 Measured by Serum Bactericidal Assay Using Human Complement (hSBA)

End point title	Number of Subjects With Neisseria Meningitidis Serogroup Y (MenY) Antibody Titers Greater Than or Equal to 1:8 Measured by Serum Bactericidal Assay Using Human Complement (hSBA) ^[8]
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End point description:

End point type	Primary
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End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	10	14	
Units: Subjects				
Year 3, hSBA-MenY, Post Fourth dose [N=20;10;14]	20	0	9	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Neisseria Meningitidis Serogroup Y (MenY) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA)

End point title	Number of Subjects With Neisseria Meningitidis Serogroup Y (MenY) Antibody Titers Greater Than or Equal to 1:8 as Measured by Serum Bactericidal Assay Using Human Complement (hSBA) ^[9]
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End point description:

End point type	Primary
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End point timeframe:

Five years after the fourth dose vaccination.

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	13	11	
Units: Subjects				
Year 5, hSBA-MenY, Post Fourth dose [N=24;13;11]	22	1	8	

Statistical analyses

No statistical analyses for this end point

Primary: Anti-PRP Geometric Mean Concentrations (GMCs)

End point title Anti-PRP Geometric Mean Concentrations (GMCs)^[10]

End point description:

End point type Primary

End point timeframe:

One year after the fourth dose vaccination.

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	51	47	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Year 1, Post Fourth dose [N=109;51;47]	27.215 (22.253 to 33.283)	19.92 (14.337 to 27.678)	10.098 (7.215 to 14.131)	

Statistical analyses

No statistical analyses for this end point

Primary: Anti-PRP Geometric Mean Concentrations (GMCs)

End point title Anti-PRP Geometric Mean Concentrations (GMCs)^[11]

End point description:

End point type Primary

End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	27	34	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Year 3, Post Fourth dose [N=55;27;34]	27.345 (21.411 to 34.924)	17.542 (11.951 to 25.748)	12.596 (8.59 to 18.471)	

Statistical analyses

No statistical analyses for this end point

Primary: Anti-PRP Geometric Mean Concentrations (GMCs)

End point title	Anti-PRP Geometric Mean Concentrations (GMCs) ^[12]
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End point description:

End point type	Primary
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End point timeframe:

Five years after the fourth dose vaccination.

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	35	31	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Year 5, Post Fourth dose [N=77;35;31]	28.349 (22.749 to 35.328)	22.854 (15.174 to 34.422)	10.693 (7.083 to 16.142)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Anti-PRP Antibody Concentrations Greater Than or Equal to 1.0 Microgram Per Milliliter

End point title	Number of Subjects With Anti-PRP Antibody Concentrations Greater Than or Equal to 1.0 Microgram Per Milliliter ^[13]
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End point description:

End point type	Primary
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End point timeframe:

One year after the fourth dose vaccination.

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	109	51	47	
Units: Subjects				
Year 1, Post Fourth dose [N=109;51;47]	108	51	47	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Anti-PRP Antibody Concentrations Greater Than or Equal to 1.0 Microgram Per Milliliter

End point title	Number of Subjects With Anti-PRP Antibody Concentrations Greater Than or Equal to 1.0 Microgram Per Milliliter ^[14]
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End point description:

End point type	Primary
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End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	55	27	34	
Units: Subjects				
Year 3, Post Fourth dose [N=55;27;34]	55	27	34	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Anti-PRP Antibody Concentrations Greater Than or Equal to 1.0 Microgram Per Milliliter

End point title	Number of Subjects With Anti-PRP Antibody Concentrations Greater Than or Equal to 1.0 Microgram Per Milliliter ^[15]
End point description:	
End point type	Primary
End point timeframe:	
Five years after the fourth dose vaccination.	
Notes:	
[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.	

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	35	31	
Units: Subjects				
Year 5, Post Fourth dose [N=77;35;31]	77	35	30	

Statistical analyses

No statistical analyses for this end point

Primary: hSBA-MenC Geometric Mean Titers (GMTs)

End point title	hSBA-MenC Geometric Mean Titers (GMTs) ^[16]
End point description:	
End point type	Primary
End point timeframe:	
One year after the fourth dose vaccination.	
Notes:	
[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.	

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	19	14	
Units: Titer				
geometric mean (confidence interval 95%)				
Year 1, hSBA-MenC, Post Fourth dose [N=35;19;14]	783.9 (416.1 to 1477)	3.2 (1.3 to 7.6)	73.3 (45 to 119.2)	

Statistical analyses

No statistical analyses for this end point

Primary: hSBA-MenC Geometric Mean Titers (GMTs)

End point title hSBA-MenC Geometric Mean Titers (GMTs)^[17]

End point description:

End point type Primary

End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	10	14	
Units: Titer				
geometric mean (confidence interval 95%)				
Year 3, hSBA-MenC, Post Fourth dose [N=19;10;14]	1002.8 (600.1 to 1675.8)	2 (2 to 2)	75.2 (27.6 to 204.7)	

Statistical analyses

No statistical analyses for this end point

Primary: hSBA-MenC Geometric Mean Titers (GMTs)

End point title hSBA-MenC Geometric Mean Titers (GMTs)^[18]

End point description:

End point type Primary

End point timeframe:

Five years after the fourth dose vaccination.

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	13	11	
Units: Titer				
geometric mean (confidence interval 95%)				
Year 5, hSBA-MenC, Post Fourth dose [N=24;13;11]	623.8 (320.9 to 1212.6)	3.9 (1.1 to 14.7)	89 (45.6 to 173.7)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With hSBA-MenC Titers Greater Than or Equal to 1:4

End point title	Number of Subjects With hSBA-MenC Titers Greater Than or Equal to 1:4 ^[19]
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End point description:

End point type	Primary
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End point timeframe:

One year after the fourth dose vaccination.

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	19	14	
Units: Subjects				
Year 1, hSBA-MenC, Post Fourth dose [N=35;19;14]	33	2	14	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With hSBA-MenC Titers Greater Than or Equal to 1:4

End point title	Number of Subjects With hSBA-MenC Titers Greater Than or Equal to 1:4 ^[20]
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End point description:

End point type	Primary
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End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	19	10	14	
Units: Subjects				
Year 3, hSBA-MenC, Post Fourth dose [N=19;10;14]	19	0	12	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With hSBA-MenC Titers Greater Than or Equal to 1:4

End point title	Number of Subjects With hSBA-MenC Titers Greater Than or Equal to 1:4 ^[21]
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End point description:

End point type	Primary
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End point timeframe:

Five years after the fourth dose vaccination.

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	13	11	
Units: Subjects				
Year 5, hSBA-MenC, Post Fourth dose [N=24;13;11]	23	2	11	

Statistical analyses

No statistical analyses for this end point

Primary: hSBA-MenY Geometric Mean Titers (GMTs)

End point title	hSBA-MenY Geometric Mean Titers (GMTs) ^[22]
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End point description:

End point type	Primary
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End point timeframe:

One year after the fourth dose vaccination.

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	19	14	
Units: Titer				
geometric mean (confidence interval 95%)				
Year 1, hSBA-MenY, Post Fourth dose [N=35;19;14]	245.7 (139.8 to 431.6)	2.7 (1.4 to 5.3)	12.2 (4.7 to 31.7)	

Statistical analyses

No statistical analyses for this end point

Primary: hSBA-MenY Geometric Mean Titers (GMTs)

End point title	hSBA-MenY Geometric Mean Titers (GMTs) ^[23]
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End point description:

End point type	Primary
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End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	10	14	
Units: Titer				
geometric mean (confidence interval 95%)				
Year 3, hSBA-MenY, Post Fourth dose [N=20;10;14]	325.4 (197.7 to 535.6)	2 (2 to 2)	15.3 (5.9 to 39.4)	

Statistical analyses

No statistical analyses for this end point

Primary: hSBA-MenY Geometric Mean Titers (GMTs)

End point title	hSBA-MenY Geometric Mean Titers (GMTs) ^[24]
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End point description:

End point type	Primary
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End point timeframe:

Five years after the fourth dose vaccination.

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	13	11	
Units: Titer				
geometric mean (confidence interval 95%)				
Year 5, hSBA-MenY, Post Fourth dose [N=24;13;11]	162.4 (75.5 to 349.6)	3.2 (1.2 to 8.7)	18.3 (6.4 to 52.4)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With hSBA-MenY Titers Greater Than or Equal to 1:4

End point title	Number of Subjects With hSBA-MenY Titers Greater Than or Equal to 1:4 ^[25]
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End point description:

End point type	Primary
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End point timeframe:

One year after the fourth dose vaccination.

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose Group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	35	19	14	
Units: Subjects				
Year 1, hSBA-MenY, Post Fourth dose [N=35;19;14]	33	1	9	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With hSBA-MenY Titers Greater Than or Equal to 1:4

End point title	Number of Subjects With hSBA-MenY Titers Greater Than or Equal to 1:4 ^[26]
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End point description:

End point type	Primary
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End point timeframe:

Three years after the fourth dose vaccination.

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	20	10	14	
Units: Subjects				
Year 3, hSBA-MenY, Post Fourth dose [N=20;10;14]	20	0	9	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With hSBA-MenY Titers Greater Than or Equal to 1:4

End point title	Number of Subjects With hSBA-MenY Titers Greater Than or Equal to 1:4 ^[27]
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End point description:

End point type	Primary
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End point timeframe:

Five years after the fourth dose vaccination.

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	MenHibrix 4-dose group	ActHIB 4-dose group	ActHIB 3-dose + MenHibrix 4th-dose group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	24	13	11	
Units: Subjects				
Year 5, hSBA-MenY, Post Fourth dose [N=24;13;11]	22	1	8	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

SAEs were collected during the entire study period, up to 5 years post fourth vaccination.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.1
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Reporting groups

Reporting group title	MenHibrix 4-dose Group
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Reporting group description:

Subjects received in the primary study (NCT00129129) 3 doses of MenHibrix co-administered with Pediarix and Pevnar and a 4th dose of MenHibrix co-administered with Pevnar. No vaccines were administered during this long-term persistence study.

Reporting group title	ActHIB 4-dose Group
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Reporting group description:

Subjects received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Pevnar and a 4th dose of ActHIB co-administered with Pevnar. No vaccines were administered during this long-term persistence study.

Reporting group title	ActHIB 3-dose + MenHibrix 4th-dose Group
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Reporting group description:

Subjects received in the primary study (NCT00129129) 3 doses of ActHIB co-administered with Pediarix and Pevnar and a dose of MenHibrix co-administered with Pevnar. No vaccines were administered during this long-term persistence study.

Serious adverse events	MenHibrix 4-dose Group	ActHIB 4-dose Group	ActHIB 3-dose + MenHibrix 4th-dose Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 138 (0.00%)	0 / 70 (0.00%)	0 / 62 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	MenHibrix 4-dose Group	ActHIB 4-dose Group	ActHIB 3-dose + MenHibrix 4th-dose Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 138 (0.00%)	0 / 70 (0.00%)	0 / 62 (0.00%)

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: No information on solicited or unsolicited adverse events was collected during this study.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 September 2009	Vaccination with GSK Biologicals' Hib-MenCY-TT conjugate vaccine was previously shown to be immunogenic and well tolerated. Results from clinical studies have demonstrated that Hib-MenCY-TT vaccine induced an immune response against the three vaccine components when a four dose series of the vaccine is administered at 2, 4, 6 and 12 to 15 months of age. In study Hib-MenCY-TT-005, subjects received either Hib-MenCY-TT vaccine or ActHIB at 2, 4, and 6 months of age. A vaccination was administered in study Hib-MenCY-TT-006 at 12 to 15 months of age: subjects that received Hib-MenCY-TT vaccine at 2, 4 and 6 months of age received a fourth dose of Hib-MenCY-TT vaccine: subjects that received ActHIB at 2, 4 and 6 months of age were re-randomized 1:1 to receive a vaccination with either Hib-MenCY-TT vaccine or ActHIB. The purpose of this study extension is to evaluate the antibody persistence at approximately 1, 3, and 5 years post-dose 4 (i.e., at 2, 4 and 6 years of age) in subjects vaccinated in study Hib-MenCY-TT-005/006.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported