Clinical trial results:
A phase IIIb randomised, open, controlled study to assess the safety, reactogenicity and immunogenicity of GlaxoSmithKline (GSK) Biologicals' 10-valent pneumococcal conjugate vaccine when co-administered with DTPa-combined, MenC and Hib-MenC vaccines in children as a 3-dose primary immunization course during the first 6 months of age.

Summary

EudraCT number	2006-000558-30
Trial protocol	DE ES
Global end of trial date	24 October 2007

Results information

Result version number	v1 (current)
This version publication date	07 March 2016
First version publication date	12 June 2015

Trial information

Trial identification

Sponsor protocol code	107005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00334334
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 Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@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	27 November 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	23 April 2007
Global end of trial reached?	Yes
Global end of trial date	24 October 2007
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to demonstrate that GSK Biologicals' 10-valent pneumococcal conjugate vaccine, when administered as a 3-dose primary vaccination course, is non-inferior to Prevenar, both co-administered with DTPa-HBV-IPV and Hib-MenC vaccines, in terms of post-immunization febrile reactions with rectal fever > 39.0°C. Criteria for safety: Non-inferiority will be demonstrated if the upper limit of the 95% CI of the difference (10Pn-PD-DiT + Hib-MenC Group minus Prevenar Group), in terms of percentage of subjects with rectal fever >39.0°C, is lower than 10%.

Protection of trial subjects:

Vaccines were administered by qualified and trained personnel and only to eligible subjects that had no contraindications to any components of the vaccines. In addition, specific adverse events (AEs) constituted absolute contraindications to further vaccination; if occurring, the subject did not receive additional doses of vaccine, continued other study procedures at the discretion of the investigator and was followed until resolution of the AE. AEs motivating ending of vaccination were any anaphylactic reaction post vaccination, acute disease at time of vaccination (= presence of moderate or severe illness with/without fever; vaccines were given in case of minor illnesses like diarrhea or mild upper respiratory infection with/without low-grade fever [i.e. Oral/Axillary/Tympanic temperature (T) < 37.5°C/Rectal T < 38.0°C] with visit postponed until improvement) and febrile illness (= oral, axillary or tympanic T ≥ 37.5°C, rectal T ≥ 38.0°C – T >= these cut-offs warranted deferral of vaccination pending recovery). Also, for the DTPa-HBV-IPV/Hib or DTPa-HBV-IPV vaccine, experience of encephalopathy (= acute, severe central nervous system disorder within 7 days post vaccination lasting more than a few hours, with failure to recover within 24 hours) constituted absolute contraindications to vaccination. For these vaccines, specific precautions were taken in case of rectal T ≥ 40.5°C or oral, axillary or tympanic T ≥ 40.0°C within 48 hours of vaccination, collapse or shock-like state (hypotonic-hyporesponsive episode) within 48 hours of vaccination, persistent, inconsolable crying within 48 hours of vaccination and lasting ≥ 3 hours and seizures with/without fever occurring within 3 days of vaccination. For Prevenar, moderate to severe illness, with/without fever was a reason to defer immunization. For NeisVac-C and Meningitec, vaccines were given with caution to individuals with thrombocytopenia or any coagulation disorder.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 June 2006
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	Spain: 519
Country: Number of subjects enrolled	Germany: 413

Country: Number of subjects enrolled	Poland: 640
Worldwide total number of subjects	1572
EEA total number of subjects	1572

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	1572
Children (2-11 years)	0
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:

The study included an Active Phase, till about 7 months of age, and an Extended Safety Follow-Up (ESFU) Phase, till about 12 months of age.

Pre-assignment

Screening details:

1572 subjects were enrolled in the study and vaccinated out of which 24 subjects from a center located in Germany (6 in each group) were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit; Safety results for these subjects are reported in this summary.

Period 1

Period 1 title	Overall Trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK 1024850A + Meningitec™ Group

Arm description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Wyeth's Men-C conjugate vaccine (Meningitec™, also referred to as Men vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of Meningitec™ at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and Meningitec™ in the lower left thigh.

Arm type	Experimental
Investigational medicinal product name	10-valent Streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn, 10Pn-PD-DiT, Synflorix™, GlaxoSmithKline (GSK) Biologicals' 1024850A vaccine, GSK1024850A
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of the vaccine were administered intramuscularly, in the lower left thigh at 2, 4 and 6 months of age.

Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-IPV-HBV/Hib, Infanrix Hexa
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses were administered intramuscularly in the lower left thigh at 2 and 4 months of age. Subjects in Poland, to comply with national recommendations, were also offered a third dose at approximately 7 months of age, after blood sampling.

Investigational medicinal product name	Meningitec™
Investigational medicinal product code	
Other name	Wyeth's conjugated meningococcal C vaccine, Meningitec™
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of the vaccine was administered, in the lower left thigh or deltoid.

Arm title	GSK 1024850A + NeisVac-C™ Group

Arm description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Baxter's Men-C conjugate vaccine (NeisVac-C™, also referred to as Neis vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of NeisVac-C™, at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and NeisVac-C™, in the lower left thigh.

Arm type	Experimental
Investigational medicinal product name	10-valent Streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn, 10Pn-PD-DiT, Synflorix™, GlaxoSmithKline (GSK) Biologicals' 1024850A vaccine, GSK1024850A
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of the vaccine were administered intramuscularly, in the lower left thigh at 2, 4 and 6 months of age.

Investigational medicinal product name	Infanrix™ Hexa
Investigational medicinal product code	
Other name	DTPa-IPV-HBV/Hib, Infanrix Hexa
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses were administered intramuscularly in the lower left thigh at 2 and 4 months of age. Subjects in Poland, to comply with national recommendations, were also offered a third dose at approximately 7 months of age, after blood sampling.

Investigational medicinal product name	NeisVac-C
Investigational medicinal product code	
Other name	Baxter's meningococcal C conjugate vaccine, NeisVac-C™
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of the vaccine was administered, in the lower left thigh or deltoid.

Arm title	GSK 1024850A + Menitorix™ Group

Arm description:

The Group is also referred to as the 10Pn-PD-DiT + Hib-MenC Group and included subjects who were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ pent (also referred to as DTPa-HBV-IPV) and with Menitorix™ (HibMenC). All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™ in the lower left thigh.

Arm type	Experimental
Investigational medicinal product name	10-valent Streptococcus pneumoniae conjugate vaccine
Investigational medicinal product code	
Other name	10Pn, 10Pn-PD-DiT, Synflorix™, GlaxoSmithKline (GSK) Biologicals' 1024850A vaccine, GSK1024850A
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of the vaccine were administered intramuscularly, in the lower left thigh at 2, 4 and 6 months of age.

Investigational medicinal product name	Infanrix penta
Investigational medicinal product code	
Other name	DTPa-HBV-IPV, Infanrix™ penta
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses were administered intramuscularly in the lower left thigh at 2 and 4 months of age. Subjects in Poland, to comply with national recommendations, were also offered a third dose at approximately 7 months of age, after blood sampling.

Investigational medicinal product name	Menitorix
Investigational medicinal product code	
Other name	GSK Biologicals' combined Haemophilus influenzae type b - meningococcal serogroup vaccine, Hib-MenC, Menitorix™
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of the vaccine were administered, in the lower left thigh at 2,4 and 6 months of age.

Arm title	Prevenar™ + Menitorix™ Group

Arm description:

The Group is also referred to as the Prevenar Group and included Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and Menitorix™, GSK Biologicals' combined Hib-MenC vaccine (also referred to as HibMenC). All vaccines were administered intramuscularly (IM), Prevenar™ in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™, in the lower left thigh.

Arm type	Active comparator
Investigational medicinal product name	Prevenar
Investigational medicinal product code	
Other name	Wyeth Lederle's 7-valent pneumococcal conjugate vaccine, 7Pn, Prevenar™
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of the vaccine were administered intramuscularly, in the lower left thigh at 2, 4 and 6 months of age.

Investigational medicinal product name	Infanrix penta
Investigational medicinal product code	
Other name	DTPa-HBV-IPV, Infanrix™ penta
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses were administered intramuscularly in the lower left thigh at 2 and 4 months of age. Subjects in Poland, to comply with national recommendations, were also offered a third dose at approximately 7 months of age, after blood sampling.

Investigational medicinal product name	Menitorix
Investigational medicinal product code	
Other name	GSK Biologicals' combined Haemophilus influenzae type b - meningococcal serogroup vaccine, Hib-MenC, Menitorix™
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of the vaccine were administered, in the lower left thigh at 2,4 and 6 months of age.

Number of subjects in period 1	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group
Started	391	393	392
Completed	376	374	373
Not completed	15	19	19
Adverse event, serious fatal	-	1	1
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	1	-	-
Other: protocol compliance issues	6	6	6
Migrated/moved from study area	-	-	-
Lost to follow-up	3	6	2
Protocol deviation	4	5	10

Number of subjects in period 1	Prevenar™ + Menitorix™ Group
Started	396
Completed	376
Not completed	20
Adverse event, serious fatal	-
Consent withdrawn by subject	1
Adverse event, non-fatal	-
Other: protocol compliance issues	6
Migrated/moved from study area	1
Lost to follow-up	3
Protocol deviation	9

Baseline characteristics

Reporting groups	
Reporting group title	GSK 1024850A + Meningitec™ Group

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Wyeth's Men-C conjugate vaccine (Meningitec™, also referred to as Men vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of Meningitec™ at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and Meningitec™ in the lower left thigh.

Reporting group title	GSK 1024850A + NeisVac-C™ Group

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Baxter's Men-C conjugate vaccine (NeisVac-C™, also referred to as Neis vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of NeisVac-C™, at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and NeisVac-C™, in the lower left thigh.

Reporting group title	GSK 1024850A + Menitorix™ Group

Reporting group description:

The Group is also referred to as the 10Pn-PD-DiT + Hib-MenC Group and included subjects who were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ pent (also referred to as DTPa-HBV-IPV) and with Menitorix™ (HibMenC). All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™ in the lower left thigh.

Reporting group title	Prevenar™ + Menitorix™ Group

Reporting group description:

The Group is also referred to as the Prevenar Group and included Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and Menitorix™, GSK Biologicals' combined Hib-MenC vaccine (also referred to as HibMenC). All vaccines were administered intramuscularly (IM), Prevenar™ in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™, in the lower left thigh.

Reporting group values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group
Number of subjects	391	393	392
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: weeks			
arithmetic mean	8.3	8.4	8.4
standard deviation	± 2.36	± 2.31	± 2.36
Gender categorical			
Units: Subjects			
Female	192	187	216
Male	199	206	176

Reporting group values	Prevenar™ + Menitorix™ Group	Total	
Number of subjects	396	1572	
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: weeks			
arithmetic mean	8.4		
standard deviation	± 2.38	-	
Gender categorical			
Units: Subjects			
Female	187	782	
Male	209	790	

End points

End points reporting groups

Reporting group title	GSK 1024850A + Meningitec™ Group

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Wyeth's Men-C conjugate vaccine (Meningitec™, also referred to as Men vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of Meningitec™ at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and Meningitec™ in the lower left thigh.

Reporting group title	GSK 1024850A + NeisVac-C™ Group

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Baxter's Men-C conjugate vaccine (NeisVac-C™, also referred to as Neis vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of NeisVac-C™, at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and NeisVac-C™, in the lower left thigh.

Reporting group title	GSK 1024850A + Menitorix™ Group

Reporting group description:

The Group is also referred to as the 10Pn-PD-DiT + Hib-MenC Group and included subjects who were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ pent (also referred to as DTPa-HBV-IPV) and with Menitorix™ (HibMenC). All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™ in the lower left thigh.

Reporting group title	Prevenar™ + Menitorix™ Group

Reporting group description:

The Group is also referred to as the Prevenar Group and included Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and Menitorix™, GSK Biologicals' combined Hib-MenC vaccine (also referred to as HibMenC). All vaccines were administered intramuscularly (IM), Prevenar™ in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™, in the lower left thigh.

Primary: Number of subjects reporting fever above (>) 39.0 degree Celsius (°C)

End point title	Number of subjects reporting fever above (>) 39.0 degree Celsius (°C)[1]

End point description:

Fever was measured as rectal temperature. Assessment of occurrences of fever > 39.0 °C was performed post doses1, 2 and 3 of 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines). This endpoint concerns subjects with at least one vaccination dose documented at the exclusion of the 24 subjects from a center located in Germany (6 in each group) were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit.

End point type	Primary

End point timeframe:

Within 4 days (Day 0-3) after each vaccination and across all doses

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Inferential analysis was only applicable and applied to the GSK 1024850A + Menitorix™

End point values	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	381	386		
Units: Subjects				
Post Dose 1 (N=381;386)	9	4		
Post Dose 2 (N=379;385)	11	11		
Post Dose 3 (N=370;375)	9	11		
Across doses (N=381;386)	23	24		

Statistical analyses

Statistical analysis title	Non-inferiority of 10Pn vs 7Pn – Post Dose 1
Comparison groups	GSK 1024850A + Menitorix™ Group v Prevenar™ + Menitorix™ Group
Number of subjects included in analysis	767
Analysis specification	Pre-specified
Analysis type	non-inferiority[2]
Parameter estimate	Difference in percentage
Point estimate	1.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.57
upper limit	3.51

Notes:

[2] - Analysis assessed the difference in percentage of subjects reporting fever >39.0°C. Non-inferiority was demonstrated if the upper limit of the standardized asymptotic 95% confidence interval of the difference (GSK 1024850A + Menitorix™ Group minus Prevenar™ + Menitorix™ Group), in terms of percentage of subjects with rectal fever >39.0°C, was lower than 10%.

Statistical analysis title	Non-inferiority of 10Pn vs 7Pn – Post Dose 2
Comparison groups	GSK 1024850A + Menitorix™ Group v Prevenar™ + Menitorix™ Group
Number of subjects included in analysis	767
Analysis specification	Pre-specified
Analysis type	non-inferiority[3]
Parameter estimate	Difference in percentage
Point estimate	0.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.45
upper limit	2.6

Notes:

[3] - Analysis assessed the difference in percentage of subjects reporting fever >39.0°C. Non-inferiority was demonstrated if the upper limit of the standardized asymptotic 95% confidence interval of the difference (GSK 1024850A + Menitorix™ Group minus Prevenar™ + Menitorix™ Group), in terms of

percentage of subjects with rectal fever >39.0°C, was lower than 10%.

Statistical analysis title	Non-inferiority of 10Pn vs 7Pn – Post Dose 3
Comparison groups	GSK 1024850A + Menitorix™ Group v Prevenar™ + Menitorix™ Group
Number of subjects included in analysis	767
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Difference in percentage
Point estimate	-0.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.04
upper limit	1.98

Notes:

[4] - Analysis assessed the difference in percentage of subjects reporting fever >39.0°C. Non-inferiority was demonstrated if the upper limit of the standardized asymptotic 95% confidence interval of the difference (GSK 1024850A + Menitorix™ Group minus Prevenar™ + Menitorix™ Group), in terms of percentage of subjects with rectal fever >39.0°C, was lower than 10%.

Statistical analysis title	Non-inferiority of 10Pn vs 7Pn – Across doses
Comparison groups	GSK 1024850A + Menitorix™ Group v Prevenar™ + Menitorix™ Group
Number of subjects included in analysis	767
Analysis specification	Pre-specified
Analysis type	non-inferiority[5]
Parameter estimate	Difference in percentage
Point estimate	-0.18
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.68
upper limit	3.32

Notes:

[5] - Analysis assessed the difference in percentage of subjects reporting fever >39.0°C. Non-inferiority was demonstrated if the upper limit of the standardized asymptotic 95% confidence interval of the difference (GSK 1024850A + Menitorix™ Group minus Prevenar™ + Menitorix™ Group), in terms of percentage of subjects with rectal fever >39.0°C, was lower than 10%.

Secondary: Number of subjects with any and any Grade 3 solicited local symptoms

End point title	Number of subjects with any and any Grade 3 solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling. Grade 3 (G3) pain was defined as crying when limb was moved/spontaneously painful. G3 swelling/redness was defined as swelling/redness larger than (>) 30 millimeters (mm). "Any" is defined as incidence of the specified symptom regardless of intensity. This endpoint concerns subjects with at least one vaccination dose documented and with results available. The 24 subjects from a center located in Germany (6 in each group) who were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit were not taken into account in this analysis.

End point type	Secondary

End point timeframe:

Within 4 days (Day 0-3) after each vaccination and across all doses

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	381	380	381	386
Units: Subjects				
Any Pain, Post Dose 1 (N=380;380;381;386)	157	157	146	120
G3 Pain, Post Dose 1 (N=380;380;381;386)	20	15	18	11
Any Redness, Post Dose 1 (N=380;380;381;386)	172	172	171	155
G3 Redness, Post Dose 1 (N=380;380;381;386)	9	4	4	3
Any Swelling, Post Dose 1 (N=380;380;381;386)	143	120	133	108
G3 Swelling, Post Dose 1 (N=380;380;381;386)	16	7	5	4
Any Pain, Post Dose 2 (N=377;376;379;385)	131	119	128	121
G3 Pain, Post Dose 2 (N=377;376;379;385)	11	13	11	9
Any Redness, Post Dose 2 (N=377;376;379;385)	180	164	178	164
G3 Redness, Post Dose 2 (N=377;376;379;385)	8	7	5	5
Any Swelling, Post Dose 2 (N=377;376;379;385)	143	122	132	113
G3 Swelling, Post Dose 2 (N=377;376;379;385)	11	9	5	6
Any Pain, Post Dose 3 (N=373;373;370;375)	100	110	123	100
G3 Pain, Post Dose 3 (N=373;373;370;375)	4	2	5	3
Any Redness, Post Dose 3 (N=373;373;370;375)	177	164	169	172
G3 Redness, Post Dose 3 (N=373;373;370;375)	11	6	3	8
Any Swelling, Post Dose 3 (N=373;373;370;375)	137	124	143	137
G3 Swelling, Post Dose 3 (N=373;373;370;375)	8	6	4	9
Any Pain, Across Doses (N=381;380;381;386)	213	208	212	185
G3 Pain, Across Doses (N=381;380;381;386)	28	26	28	20
Any Redness, Across Doses (N=381;380;381;386)	255	236	242	239
G3 Redness, Across Doses (N=381;380;381;386)	21	16	9	12
Any Swelling, Across Doses (N=381;380;381;386)	216	189	207	190
G3 Swelling, Across Doses (N=381;380;381;386)	28	20	12	17

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and any Grade 3 solicited general symptoms

End point title	Number of subjects with any and any Grade 3 solicited general symptoms

End point description:

Solicited general symptoms assessed include drowsiness (Drows), fever, irritability (Irr), and loss of appetite (Loss App). Grade 3 (G3) Drows was defined as drowsiness which prevented normal everyday activities. G3 fever was defined as fever (rectal temperature) above (>) 39.0 degree Celsius (°C). G3 Irr was defined as crying that could not be comforted/preventing normal everyday activities. G3 Loss App was defined as the subject not eating at all. "Any" is defined as incidence of the specified symptom regardless of intensity or relationship to study vaccination. This endpoint concerns subjects with at least one vaccination dose documented and with results available. The 24 subjects from a center located in Germany (6 in each group) who were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit were not taken into account in this analysis.

End point type	Secondary

End point timeframe:

Within 4 days (Day 0-3) after each vaccination dose (D) and across all doses (AD)

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	381	380	381	386
Units: Subjects				
Any Drows, Post D1 (N=381;380;381;386)	211	218	199	156
G3 Drows, Post D1 (N=381;380;381;386)	8	9	7	5
Any Fever, Post D1 (N=381;380;381;386)	166	192	141	95
G3 Fever, Post D1 (N=381;380;381;386)	12	15	9	4
Any Irr , Post D1 (N=381;380;381;386)	230	241	223	194
G3 Irr, Post D1 (N=381;380;381;386)	27	16	18	15
Any Loss App, Post D1 (N=381;380;381;386)	126	128	134	98
G3 Loss App, Post D1 (N=381;380;381;386)	6	3	1	1
Any Drows, Post D2 (N=377;376;379;385)	168	174	176	161
G3 Drows, Post D2 (N=377;376;379;385)	4	6	2	5
Any Fever, Post D2 (N=377;376;379;385)	169	156	138	142

G3 Fever, Post D2 (N=377;376;379;385)	15	17	11	11
Any Irr , Post D2 (N=377;376;379;385)	215	197	217	193
G3 Irr, Post D2 (N=377;376;379;385)	18	16	20	12
Any Loss App, Post D2 (N=377;376;379;385)	118	112	111	120
G3 Loss App, Post D2 (N=377;376;379;385)	1	2	0	2
Any Drows, Post D3 (N=373;373;370;375)	115	126	117	107
G3 Drows, Post D3 (N=373;373;370;375)	2	2	1	3
Any Fever, Post D3 (N=373;373;370;375)	90	87	90	89
G3 Fever, Post D3 (N=373;373;370;375)	14	12	9	11
Any Irr , Post D3 (N=373;373;370;375)	162	150	158	138
G3 Irr, Post D3 (N=373;373;370;375)	9	13	3	7
Any Loss App, Post D3 (N=373;373;370;375)	95	83	89	96
G3 Loss App, Post D3 (N=373;373;370;375)	1	3	1	2
Any Drows, AD (N=381;380;381;386)	268	276	265	252
G3 Drows, AD (N=381;380;381;386)	13	15	10	13
Any Fever, AD (N=381;380;381;386)	247	258	223	218
G3 Fever, AD (N=381;380;381;386)	36	40	23	24
Any Irr , AD (N=381;380;381;386)	301	294	293	281
G3 Irr, AD (N=381;380;381;386)	49	40	38	31
Any Loss App, AD (N=381;380;381;386)	203	200	209	196
G3 Loss App, AD (N=381;380;381;386)	8	7	2	4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with unsolicited adverse events (AEs)

End point title	Number of subjects with unsolicited adverse events (AEs)

End point description:

An AE is any untoward medical occurrence in a clinical investigation subject, temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product. “Any” is defined an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination. This endpoint concerns subjects with at least one vaccination dose documented. The 24 subjects from a center located in Germany (6 in each group) who were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit were not taken into account in this analysis.

End point type	Secondary

End point timeframe:

Within 31 days (Day 0-30) after each vaccination, across doses

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	385	387	386	390
Units: Subjects				
Any unsolicited AE(s)	144	142	144	153

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs) in vaccinated subjects

End point title	Number of subjects with serious adverse events (SAEs) in vaccinated subjects

End point description:

An SAE is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or may evolve into one of the outcomes listed above. "Any" is defined an incidence of a SAE regardless of intensity/severity. This endpoint concerns subjects with at least one vaccination dose documented at the exclusion of the 24 subjects from a center located in Germany (6 in each group) were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit.

End point type	Secondary

End point timeframe:

Throughout the Active Phase of the study, from first vaccination at 6-16 weeks of age till approximately 7 months of age.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	385	387	386	390
Units: Subjects				
Any SAE(s)	8	14	10	13

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs) in enrolled subjects who were eliminated from the study efficacy analyses

End point title	Number of subjects with serious adverse events (SAEs) in enrolled subjects who were eliminated from the study efficacy analyses

End point description:

An SAE is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or may evolve into one of the outcomes listed above. “Any” is defined an incidence of a SAE regardless of intensity/severity. This endpoint concerns the 24 subjects from a center located in Germany (6 in each group) were later eliminated from analyses due to protocol compliance following findings of a for cause audit.

End point type	Secondary

End point timeframe:

Throughout the Active Phase of the study, from first vaccination at 6-16 weeks of age till approximately 7 months of age.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: Subjects				
Any SAE(s)	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serious adverse events (SAEs)

End point title	Number of subjects with serious adverse events (SAEs)

End point description:

An SAE is any untoward medical occurrence that: results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, or may evolve into one of the outcomes listed above. “Any” is defined an incidence of a SAE regardless of intensity/severity. This endpoint concerns all subjects enrolled in the study, that is, eligible subjects with at least one vaccination dose documented (please refer to endpoint “Number of subjects with serious adverse events (SAEs) in vaccinated subjects” for a description of these subjects) and the 24 subjects from a center located in Germany (6 in each group) who were later eliminated from analyses due to protocol compliance following findings of a for cause audit.

End point type	Secondary

End point timeframe:

Throughout the entire study, from 1st vaccination at 6-16 weeks of age till the end of the ESFU Phase, when subjects reached approximately 12 months of age.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	391	393	392	396
Units: Subjects				
Any SAE(s)	24	30	30	28

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations above or equal to (>=-) 0.20 microgram per liter (µg/mL)

End point title	Number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations above or equal to (>=-) 0.20 microgram per liter (µg/mL)

End point description:

The number of subjects with anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations (Anti-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F) above or equal to >= 0.20 µg/mL was tabulated. The seroprotection and seropositivity cut-off values for the assay were >= 0.20 µg/mL and >= 0.05 µg/mL, respectively. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	169	175	173	170
Units: Subjects				
Anti 1, at M5 (N=169;174;173;170)	163	170	161	1
Anti 4, at M5 (N=169;174;173;170)	169	173	170	170
Anti-5, at M5 (N=169;174;173;168)	169	174	171	4
Anti 6B, at M5 (N=169;175;173;169)	159	155	151	157
Anti 7F, at M5 (N=169;175;173;169)	169	174	171	5
Anti 9V, at M5 (N=169;175;173;169)	167	171	170	167
Anti 14, at M5 (N=169;175;173;169)	169	175	173	168
Anti 18C, at M5 (N=169;175;173;169)	167	173	172	167
Anti 19F, at M5 (N=169;175;173;170)	166	174	171	170
Anti 23F, at M5 (N=169;175;173;169)	162	168	160	159

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations

End point title	Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations

End point description:

Anti-pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F antibody concentrations (Anti-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F) were calculated, expressed as geometric mean concentrations (GMCs) and tabulated. The seropositivity cut-off for the assay was >= 0.05 microgram per millilitre (µg/mL). Antibody concentrations or titres < 0.05 µg/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	169	175	173	170
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti 1, at M5 (N=169;174;173;170)	1.17 (1.03 to 1.33)	1.09 (0.96 to 1.24)	1 (0.86 to 1.15)	0.03 (0.03 to 0.03)
Anti 4, at M5 (N=169;174;173;170)	1.88 (1.7 to 2.09)	1.96 (1.76 to 2.19)	1.7 (1.52 to 1.92)	2.78 (2.46 to 3.14)
Anti-5, at M5 (N=169;174;173;168)	1.96 (1.78 to 2.17)	1.87 (1.69 to 2.08)	1.69 (1.49 to 1.91)	0.03 (0.03 to 0.04)
Anti 6B, at M5 (N=169;175;173;169)	0.96 (0.82 to 1.12)	0.85 (0.72 to 1.01)	0.71 (0.59 to 0.86)	1.32 (1.12 to 1.57)
Anti 7F, at M5 (N=169;175;173;169)	2.82 (2.54 to 3.14)	2.57 (2.32 to 2.86)	2.25 (1.98 to 2.55)	0.04 (0.03 to 0.04)
Anti 9V, at M5 (N=169;175;173;169)	1.77 (1.58 to 2)	1.72 (1.52 to 1.95)	1.58 (1.4 to 1.77)	3.17 (2.75 to 3.64)
Anti 14, at M5 (N=169;175;173;169)	3.75 (3.25 to 4.31)	3.79 (3.37 to 4.26)	3.36 (2.91 to 3.88)	5.97 (5.05 to 7.07)
Anti 18C, at M5 (N=169;175;173;169)	2.43 (2.07 to 2.84)	3.92 (3.38 to 4.54)	2.34 (2.01 to 2.71)	3.01 (2.65 to 3.42)
Anti 19F, at M5 (N=169;175;173;170)	4.93 (4.28 to 5.68)	4.71 (4.09 to 5.42)	3.81 (3.32 to 4.37)	2.56 (2.29 to 2.86)
Anti 23F, at M5 (N=169;175;173;169)	1.3 (1.13 to 1.49)	1.2 (1.02 to 1.4)	0.96 (0.82 to 1.13)	2.46 (2.04 to 2.98)

Statistical analyses

No statistical analyses for this end point

Secondary: Opsonophagocytic activity (OPA) titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F

End point title	Opsonophagocytic activity (OPA) titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F

End point description:

OPA titers against pneumococcal serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F (OPA Anti-1, -4, -5, -6B, -7F, -9V, -14, -18C, -19F and -23F) were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seropositivity cut-off for the assay was >= 8. Antibody titers < 8 were given an arbitrary value of half the cut-off for the purpose of GMT calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	162	168	161	156
Units: Titers				
geometric mean (confidence interval 95%)				
OPA Anti-1, at M5 (N=162;168;161;156)	23.9 (17.9 to 32)	18.8 (14.4 to 24.4)	19.7 (14.9 to 26.1)	4.2 (3.9 to 4.5)
OPA Anti-4, at M5 (N=154;159;159;154)	697.4 (617.8 to 787.3)	755.6 (660.9 to 863.7)	669.8 (553.8 to 810)	926.2 (779.5 to 1100.4)
OPA Anti-5, at M5 (N=153;163;159;153)	91.7 (72.7 to 115.7)	71.4 (56.5 to 90.4)	77.4 (61 to 98.2)	4.2 (4 to 4.5)
OPA Anti-6B, at M5 (N=148;150;148;151)	459.1 (334.2 to 630.8)	404.6 (287.7 to 569.1)	354.2 (243.4 to 515.3)	1575.3 (1230.8 to 2016)
OPA Anti-7F, at M5 (N=149;164;158;138)	2513.3 (2106.1 to 2999.3)	2821.3 (2297.9 to 3463.9)	2290.5 (1802.3 to 2910.9)	8.7 (6.3 to 11.9)
OPA Anti-9V, at M5 (N=153;153;155;150)	1005.6 (825.3 to 1225.2)	1108.8 (905.9 to 1357.1)	1122.6 (938.9 to 1342.3)	1305 (1046.3 to 1627.6)
OPA Anti-14, at M5 (N=154;167;160;154)	797.8 (655.3 to 971.2)	879 (709.1 to 1089.5)	779.9 (628.1 to 968.3)	1539.4 (1230.2 to 1926.2)
OPA Anti-18C, at M5 (N=155;163;157;149)	174.9 (144.1 to 212.3)	282.8 (234.7 to 340.8)	142.7 (113.8 to 179.1)	212.8 (174.9 to 258.9)
OPA Anti-19F, at M5 (N=157;165;159;147)	387.5 (305 to 492.2)	298.4 (230.3 to 386.7)	261 (200.9 to 339)	52 (40.8 to 66.4)
OPA Anti-23F, at M5 (N=146;156;146;148)	1066 (811.9 to 1399.6)	1219.6 (930.7 to 1598.2)	880.7 (633.1 to 1225.1)	5469.2 (4410.2 to 6782.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations to protein D (Anti-PD)

End point title	Antibody concentrations to protein D (Anti-PD)

End point description:

Anti-protein D (Anti-PD) antibody concentrations by Enzyme-Linked Immunosorbent Assay (ELISA) were calculated, expressed as geometric mean concentrations (GMCs) in ELISA unit per milli-liter (EL.U/mL) and tabulated. The seropositivity cut-off for the assay was >= 100 EL.U/mL. Antibody concentrations < 100 EL.U/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168	174	173	163
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PD, at M5	2114 (1847.6 to 2418.8)	1715.5 (1494.9 to 1968.7)	1726.7 (1493.3 to 1996.7)	72.3 (64.5 to 81.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-pertussis toxoid (Anti-PT), anti- filamentous haemagglutinin (Anti-FHA) and anti-pertactin (Anti-PRN) antibody concentrations

End point title	Anti-pertussis toxoid (Anti-PT), anti- filamentous haemagglutinin (Anti-FHA) and anti-pertactin (Anti-PRN) antibody concentrations

End point description:

Anti-PT, Anti-FHA and Anti-PRN concentrations measured by Enzyme-Linked Immunosorbent Assay (ELISA) were calculated, expressed as geometric mean concentrations (GMCs) in ELISA unit per milli-liter (EL.U/mL) and tabulated. The seropositivity cut-off for the assay was >= 5 EL.U/mL. Antibody concentrations < 5 EL.U/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168	174	173	168
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-PT, at M5 (N=168;174;172;166)	38.4 (34.9 to 42.4)	43.1 (39.1 to 47.5)	42.2 (38.3 to 46.6)	43.2 (39.6 to 47.1)
Anti-FHA, at M5 (N=168;174;173;168)	162.6 (147.1 to 179.7)	184.3 (165.8 to 204.9)	189.2 (172.8 to 207.3)	191.2 (174 to 210.2)
Anti-PRN, at M5 (N=168;174:173;168)	95.1 (84.4 to 107.2)	107.5 (94 to 123)	99.9 (87.4 to 114.2)	110.5 (97.5 to 125.1)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-diphtheria (Anti-D) and anti-tetanus toxoids (Anti-TT) antibody concentrations

End point title	Anti-diphtheria (Anti-D) and anti-tetanus toxoids (Anti-TT) antibody concentrations

End point description:

Anti-D and Anti-TT antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in International units per milliliter (IU/mL), and tabulated. The seropositivity cut-off for the assay was >= 0.1 IU/mL. Antibody concentrations < 0.1 IU/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	169	175	173	169
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, at M5	2.808 (2.521 to 3.127)	2.263 (1.975 to 2.593)	2.436 (2.137 to 2.778)	2.615 (2.316 to 2.952)
Anti-TT, at M5	3.522 (3.185 to 3.896)	5.259 (4.828 to 5.729)	4.508 (4.134 to 4.916)	3.566 (3.265 to 3.895)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

End point title	Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

End point description:

Anti-PRP antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter (µg/mL), and tabulated. The seroprotection cut-off for the assay for the purpose of this endpoint was >= 0.15 µg/mL. Antibody concentrations < 0.15 µg/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	171	178	174	172
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP, at M4	1.429 (1.124 to 1.816)	2.704 (2.212 to 3.306)	1.99 (1.575 to 2.514)	1.591 (1.249 to 2.026)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

End point title	Anti-polyribosyl-ribitol-phosphate (Anti-PRP) antibody concentrations

End point description:

Anti-PRP antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter (µg/mL), and tabulated. The seroprotection cut-off for the assay for the purpose of this endpoint was >= 0.15 µg/mL. Antibody concentrations < 0.15 µg/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168	174	172	170
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP, at M5	4.343 (3.556 to 5.304)	6.708 (5.762 to 7.81)	13.746 (11.406 to 16.567)	10.947 (9.165 to 13.077)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-hepatitis B surface antigen (HBs) antibody concentrations

End point title	Anti-hepatitis B surface antigen (HBs) antibody concentrations

End point description:

Anti-HBs antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in milli-International unit per milliliter (IU/mL), and tabulated per country (Germany, Poland, Spain) and in total – across all countries. The seropositivity cut-off for the assay was >= 10 mIU/mL. Antibody concentrations < 10 mIU/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	62	80	89	64
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HBs, In Germany, at M5 (N=12;17;16;9)	516 (289 to 921.2)	550.2 (246.4 to 1228.6)	533.9 (222.3 to 1282.2)	464.9 (262 to 825.1)
Anti-HBs, In Poland, at M5 (N=24;34;41;25)	1100.7 (819.9 to 1477.7)	1037.1 (868.4 to 1238.7)	925.4 (662.6 to 1292.3)	739.9 (542.3 to 1009.7)
Anti-HBs, In Spain, at M5 (N=26;29;32;30)	863.5 (609.8 to 1222.8)	684 (384.2 to 1218)	913.1 (655.4 to 1272)	908 (664.4 to 1241)
Anti-HBs, In Total, at M5 (N=62;80;89;64)	858.6 (692.9 to 1063.9)	779.5 (594.3 to 1022.4)	834.2 (655.4 to 1061.8)	762.9 (622.9 to 934.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers

End point title	Anti-polio type 1, 2 and 3 (Anti-Polio 1, 2 and 3) antibody titers

End point description:

Anti-Polio 1, 2 and 3 antibody titers were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seroprotection cut-off for the assay was >= 8. Antibody titers < 8 were given an arbitrary value of half the cut-off for the purpose of GMT calculation. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	39	44	49	41
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-Polio 1, at M5 (N=39;44;49;41)	284.9 (191.6 to 423.6)	427.2 (301.1 to 606.3)	454.2 (319.6 to 645.4)	371.3 (247 to 558.1)
Anti-Polio 2, at M5 (N=31;42;46;32)	327.1 (196.7 to 543.9)	251.8 (176.2 to 359.9)	263.8 (170.8 to 407.6)	298.2 (184.8 to 481.3)

Anti-Polio 3, at M5 (N=34;36;49;38)	572.8 (361.7 to 907.3)	608.9 (413.6 to 896.5)	590 (402.7 to 864.5)	666.5 (410.6 to 1081.7)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polysaccharide C (Anti-PSC) antibody concentrations >= 2.0 micrograms per milliiter (µg/mL)

End point title	Number of subjects with anti-polysaccharide C (Anti-PSC) antibody concentrations >= 2.0 micrograms per milliiter (µg/mL)

End point description:

The number of subjects with Anti-PSC above or equal to >= 2.0 µg/mL was tabulated. The seroprotection and seropositivity cut-off values for the assay were >= 2.0 µg/mL and >= 0.30 µg/mL, respectively. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	178	174	171
Units: Subjects				
Anti PSC >=2.0 µg/mL, at M4 (N=170;178;174;171)	163	172	159	154

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polysaccharide C (Anti-PSC) antibody concentrations

End point title	Anti-polysaccharide C (Anti-PSC) antibody concentrations

End point description:

Anti-PSC antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter (µg/mL), and tabulated. The seropositivity cut-off for the assay was >= 0.30 µg/mL. Antibody concentrations < 0.30 µg/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Seroprotection status, defined as: Anti-PRP antibody concentrations ≥ 0.15 and ≥ 1.0 µg/mL. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available

for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	170	178	174	171
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSC, at M4 (N=170;178;174;171)	5.96 (5.42 to 6.57)	7.99 (7.28 to 8.77)	6.1 (5.47 to 6.8)	5.64 (5.05 to 6.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polysaccharide C (Anti-PSC) antibody concentrations >= 2.0 microgram per milliiter (µg/mL)

End point title	Number of subjects with anti-polysaccharide C (Anti-PSC) antibody concentrations >= 2.0 microgram per milliiter (µg/mL)

End point description:

The number of subjects with Anti-PSC above or equal to >= 2.0 µg/mL was tabulated. The seroprotection and seropositivity cut-off values for the assay were >= 2.0 µg/mL and >= 0.30 µg/mL, respectively. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168	174	173	169
Units: Subjects				
Anti-PSC >=2.0 µg/mL, at M5 (N=168;174;173;169)	138	160	166	161

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-polysaccharide C (Anti-PSC) antibody concentrations

End point title	Anti-polysaccharide C (Anti-PSC) antibody concentrations

End point description:

Anti-PSC antibody concentrations were calculated, expressed as geometric mean concentrations (GMCs), in microgram per milliliter (µg/mL), and tabulated. The seropositivity cut-off for the assay was >= 0.30 µg/mL. Antibody concentrations < 0.30 µg/mL were given an arbitrary value of half the cut-off for the purpose of GMC calculation. Seroprotection status, defined as: Anti-PRP antibody concentrations ≥ 0.15 and ≥ 1.0 µg/mL. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	168	174	173	169
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PSC, at M5 (N=168;174;173;169)	4.08 (3.64 to 4.56)	5.64 (5.13 to 6.2)	7.27 (6.59 to 8.01)	6.17 (5.58 to 6.81)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers >= 128

End point title	Number of subjects with serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers >= 128

End point description:

The number of subjects with rSBA-MenC) antibody titres above or equal to >= 128 was tabulated. The seroprotection cut-off value for the assay was >= 8. Analysis for this endpoint was performed on eligible

subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	165	177	168	166
Units: Subjects				
rSBA-MenC>=128, at M4 (N=165;177;168;166)	160	172	150	146

Statistical analyses

No statistical analyses for this end point

Secondary: Serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers

End point title	Serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers

End point description:

rSBA-MenC antibody titres were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seroprotection cut-off value for the assay was >= 8. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 4 (M4), aka 2 months after the administration of the 2nd dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	165	177	168	166
Units: Titers				
geometric mean (confidence interval 95%)				

rSBA-MenC, at M4 (N=165;177;168;166)	1299.8 (1082 to 1561.5)	1474.2 (1263.3 to 1720.4)	501.8 (410.3 to 613.6)	480.4 (399.1 to 578.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers >= 128

End point title	Number of subjects with serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers >= 128

End point description:

The number of subjects with rSBA-MenC) antibody titres above or equal to >= 128 was tabulated. The seroprotection cut-off value for the assay was >= 8. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	138	137	120
Units: Subjects				
rSBA-MenC>=128, at M5 (N=126;138;137;120)	118	134	133	114

Statistical analyses

No statistical analyses for this end point

Secondary: Serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers

End point title	Serum bactericidal assay (performed using baby rabbit complement) for Neisseria meningitidis serogroups C (rSBA-MenC) antibody titers

End point description:

rSBA-MenC antibody titres were calculated, expressed as geometric mean titers (GMTs) and tabulated. The seroprotection cut-off value for the assay was >= 8. Analysis for this endpoint was performed on eligible subjects with at least one vaccination dose documented (please refer to endpoint "Number of

subjects with serious adverse events (SAEs) in vaccinated subjects" for a description of these subjects) for whom assay results were available for antibodies against at least one study vaccine antigen component after vaccination.

End point type	Secondary

End point timeframe:

At Month 5 (M5), aka one month after the administration of the third dose of the primary vaccination course with 10Pn-PD-DiT or 7Pn vaccine co-administered with DTPa-combined, MenC or Hib-MenC vaccines.

End point values	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group	Prevenar™ + Menitorix™ Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	138	137	120
Units: Titers				
geometric mean (confidence interval 95%)				
rSBA-MenC, at M5 (N=126;138;137;120)	665.2 (528.8 to 836.8)	1152.6 (958.4 to 1386.3)	1590.9 (1298.5 to 1949.1)	1207.7 (964.4 to 1512.3)

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms and unsolicited AEs: within 4 and 31 days post vaccination, across doses, respectively. SAEs: Between Dose 1 at 6-16 weeks of age till the end of the ESFU Phase, when subjects reached approximately 12 months of age.

Adverse event reporting additional description:

Occurrences of reported AEs (all/related) were not available and are encoded as equal to the number of subjects affected. Note that safety events reported below include the SAEs reported for the 24 subjects from a center located in Germany (6 in each group) who were excluded from efficacy analyses due to protocol compliance issues.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	11.0

Reporting groups

Reporting group title	GSK 1024850A + Meningitec™ Group

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Wyeth's Men-C conjugate vaccine (Meningitec™, also referred to as Men vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of Meningitec™ at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and Meningitec™ in the lower left thigh.

Reporting group title	GSK 1024850A + NeisVac-C™ Group

Reporting group description:

Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ hexa (also referred to as DTPa-HBV-IPV/Hib). In addition, subjects also received Baxter's Men-C conjugate vaccine (NeisVac-C™, also referred to as Neis vaccine) at 2 and 4 months of age. For subjects in Poland and to comply with national recommendations, subjects were also offered a third dose of NeisVac-C™, at approximately 7 months of age, after the blood sampling performed at that time point. All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ hexa in the upper left thigh and NeisVac-C™, in the lower left thigh.

Reporting group title	GSK 1024850A + Menitorix™ Group

Reporting group description:

The Group is also referred to as the 10Pn-PD-DiT + Hib-MenC Group and included subjects who were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (also referred to as 10Pn-PD-DiT or 10Pn vaccine) co-administered with Infanrix™ pent (also referred to as DTPa-HBV-IPV) and with Menitorix™ (HibMenC). All vaccines were administered intramuscularly (IM), 10Pn in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™ in the lower left thigh.

Reporting group title	Prevenar™ + Menitorix™ Group

Reporting group description:

The Group is also referred to as the Prevenar Group and included Subjects were vaccinated with a 3-dose course administered at 2, 4 and 6 months of age of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and Menitorix™, GSK Biologicals' combined Hib-MenC vaccine (also referred to as HibMenC). All vaccines were administered intramuscularly (IM), Prevenar™ in the right thigh, Infanrix™ penta in the upper left thigh and Menitorix™, in the lower left thigh.

Serious adverse events	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 391 (6.14%)	30 / 393 (7.63%)	30 / 392 (7.65%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	3 / 391 (0.77%)	3 / 393 (0.76%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Apnoea			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Allergic bronchitis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fracture			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile convulsion			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iron deficiency anaemia			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroesophageal reflux disease			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspepsia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatosplenomegaly			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Dermatitis atopic			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urticaria			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Cystitis noninfective			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Rickets			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 391 (0.77%)	2 / 393 (0.51%)	2 / 392 (0.51%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 391 (0.77%)	6 / 393 (1.53%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 3	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			

subjects affected / exposed	0 / 391 (0.00%)	4 / 393 (1.02%)	2 / 392 (0.51%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	2 / 391 (0.51%)	2 / 393 (0.51%)	3 / 392 (0.77%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 391 (0.51%)	3 / 393 (0.76%)	8 / 392 (2.04%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	4 / 391 (1.02%)	1 / 393 (0.25%)	4 / 392 (1.02%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 391 (0.00%)	2 / 393 (0.51%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess of eyelid			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis escherichia coli			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	1 / 391 (0.26%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			

subjects affected / exposed	0 / 391 (0.00%)	3 / 393 (0.76%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumococcal sepsis			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis acute			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 391 (0.26%)	1 / 393 (0.25%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 391 (0.00%)	2 / 393 (0.51%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 391 (0.00%)	3 / 393 (0.76%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			

subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Kawasaki’s disease			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Measles			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Otitis media acute			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pseudocroup			

subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 391 (0.00%)	1 / 393 (0.25%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 391 (0.00%)	0 / 393 (0.00%)	1 / 392 (0.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Amino acid metabolism disorder			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vitamin b complex deficiency			
subjects affected / exposed	1 / 391 (0.26%)	0 / 393 (0.00%)	0 / 392 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Prevenar™ + Menitorix™ Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	28 / 396 (7.07%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Haemangioma			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 396 (0.51%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
Genital labial adhesions			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchitis chronic			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Apnoea			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Allergic bronchitis			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wheezing			

subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fracture			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Contusion			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Febrile convulsion			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Iron deficiency anaemia			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 396 (0.76%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Gastroesophageal reflux disease			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dyspepsia			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Enteritis			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatosplenomegaly			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urticaria			

subjects affected / exposed	0 / 396 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				
subjects affected / exposed	0 / 396 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Cystitis noninfective				
subjects affected / exposed	0 / 396 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Rickets				
subjects affected / exposed	0 / 396 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchitis				
subjects affected / exposed	1 / 396 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	3 / 396 (0.76%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	1 / 396 (0.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Bronchiolitis				
subjects affected / exposed	0 / 396 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Gastroenteritis			
subjects affected / exposed	5 / 396 (1.26%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	3 / 396 (0.76%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abscess of eyelid			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis escherichia coli			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis salmonella			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumococcal sepsis			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			

subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis rotavirus			
subjects affected / exposed	3 / 396 (0.76%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis norovirus			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastroenteritis viral			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infectious mononucleosis			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Kawasaki’s disease			

subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Measles			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Meningitis viral			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Otitis media acute			
subjects affected / exposed	1 / 396 (0.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pseudocroup			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory tract infection			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Upper respiratory tract infection			

subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 396 (0.51%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Amino acid metabolism disorder			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vitamin b complex deficiency			
subjects affected / exposed	0 / 396 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	GSK 1024850A + Meningitec™ Group	GSK 1024850A + NeisVac-C™ Group	GSK 1024850A + Menitorix™ Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	301 / 391 (76.98%)	294 / 393 (74.81%)	293 / 392 (74.74%)
General disorders and administration site conditions			
Pain			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	213 / 381 (55.91%)	208 / 380 (54.74%)	212 / 381 (55.64%)
occurrences (all)	213	208	212
Redness			
alternative dictionary used: MedDRA 10.0			

alternative assessment type: Systematic			
subjects affected / exposed[2]	255 / 381 (66.93%)	236 / 380 (62.11%)	242 / 381 (63.52%)
occurrences (all)	255	236	242
Swelling			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	216 / 381 (56.69%)	189 / 380 (49.74%)	207 / 381 (54.33%)
occurrences (all)	216	189	207
Drowsiness			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	268 / 381 (70.34%)	276 / 380 (72.63%)	265 / 381 (69.55%)
occurrences (all)	268	276	265
Fever >= 38.0°C			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	247 / 381 (64.83%)	258 / 380 (67.89%)	223 / 381 (58.53%)
occurrences (all)	247	258	223
Irritability			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	301 / 381 (79.00%)	294 / 380 (77.37%)	293 / 381 (76.90%)
occurrences (all)	301	294	293
Loss of appetite			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[7]	203 / 381 (53.28%)	200 / 380 (52.63%)	209 / 381 (54.86%)
occurrences (all)	203	200	209
Infections and infestations			
Upper respiratory tract infection			
alternative dictionary used: MedDRA 10.0			
subjects affected / exposed[8]	30 / 385 (7.79%)	30 / 387 (7.75%)	28 / 386 (7.25%)
occurrences (all)	30	30	28

Non-serious adverse events	Prevenar™ + Menitorix™ Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	281 / 396 (70.96%)		
General disorders and administration site conditions			
Pain			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[1]	185 / 386 (47.93%)		
occurrences (all)	185		
Redness			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[2]	239 / 386 (61.92%)		
occurrences (all)	239		
Swelling			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[3]	190 / 386 (49.22%)		
occurrences (all)	190		
Drowsiness			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[4]	252 / 386 (65.28%)		
occurrences (all)	252		
Fever >= 38.0°C			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[5]	218 / 386 (56.48%)		
occurrences (all)	218		
Irritability			
alternative dictionary used: MedDRA 10.0			
alternative assessment type: Systematic			
subjects affected / exposed[6]	281 / 386 (72.80%)		
occurrences (all)	281		

Loss of appetite alternative dictionary used: MedDRA 10.0 alternative assessment type: Systematic subjects affected / exposed[7] occurrences (all)	196 / 386 (50.78%) 196		
Infections and infestations Upper respiratory tract infection alternative dictionary used: MedDRA 10.0 subjects affected / exposed[8] occurrences (all)	32 / 390 (8.21%) 32		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[2] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[3] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[4] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[5] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[6] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[7] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: Analysis for this Event was only performed on subjects for whom the specified symptom was reported.

[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: This event only concerns subjects with at least one vaccination dose documented at the exclusion of the 24 subjects from a center located in Germany (6 in each group) were later eliminated and excluded from efficacy analyses due to protocol compliance following findings of a for cause audit.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported