Clinical trial results:
A phase III, open, controlled study to assess the safety, reactogenicity and immunogenicity of GlaxoSmithKline (GSK) Biologicals' 10-valent pneumococcal conjugate vaccine or Prevenar when given as a booster dose between 11-18 months of age in children previously vaccinated in the primary study 10PN-PD-DIT-011 (107005) with either GSK Biologicals' 10-valent pneumococcal conjugate vaccine or Prevenar.

Summary

EudraCT number	2006-005733-38
Trial protocol	DE ES PL
Global end of trial date	14 June 2008

Results information

Result version number	v1
This version publication date	22 March 2016
First version publication date	05 December 2014

Trial information

Trial identification

Sponsor protocol code	109507

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00463437
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium,
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	08 December 2008
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 June 2008
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 a booster dose GSK Biologicals' 10-valent pneumococcal conjugate vaccine 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 in children at 11 to 18 months of age.
Criteria for safety: Non-inferiority will be demonstrated if one can rule out an increase, in terms of percentage of subjects with rectal fever >39.0°C (10Pn+Hib-MenC group as compared to Prevenar group) above 5% + half the incidence in the control group (= null hypothesis) as shown by an one-sided P-value < 2.5%.

Protection of trial subjects:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms. Thereafter, the safety follow-up phase of the study aimed at ensuring continued assessment of the safety of the subjects participating to the study for a duration of about 6 months (minimum 180 days) after the administration of the booster dose of the study vaccines to each subject. Towards this, subjects were followed up for 6 months via contacts with the parents/guardians by phone to determine if the subject had experienced a serious adverse event during this time period.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	25 April 2007
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	Germany: 341
Country: Number of subjects enrolled	Spain: 463
Country: Number of subjects enrolled	Poland: 633
Worldwide total number of subjects	1437
EEA total number of subjects	1437

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)	1437
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: -

Pre-assignment

Screening details:

Activities performed pre vaccination during the screening phase included the following: check for inclusion criteria, exclusion criteria, contraindications/precautions, elimination criteria and medical history of subjects. Thereafter, informed consents were signed by the parent(s)/guardian(s) of the subjects.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™

Arm description:

Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (10Pn) co-administered with Infanrix™ IPV Hib and Wyeth's Men-C conjugate vaccine (Meningitec™) received a booster dose of the 10Pn vaccine co-administered with GSK Biologicals' DTPa-combined vaccine (either Infanrix™ hexa in Germany and Poland or Infanrix™ IPV Hib in Spain) and Meningitec™ at 11-18 months of age. All vaccines were administered intramuscularly in the thigh for children aged <12 months or in the thigh or deltoid for children aged ≥ 12 months. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ hexa and Infanrix™ IPV Hib vaccines were administered in the upper left thigh or deltoid; and Meningitec™ was administered in the lower left thigh or deltoid.

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

Dosage and administration details:

One dose of the vaccine was administered in the right thigh or deltoid.

Investigational medicinal product name	Infanrix IPV + Hib
Investigational medicinal product code	
Other name	DTPa- IPV/Hib, Infanrix IPV Hib, GSK Biologicals' diphtheria-tetanus-acellular pertussis-inactivated poliovirus and Haemophilus influenzae type b vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

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.

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	DTPa-IPV-HBV / Hib, GSK Biologicals' diphtheria-tetanus-acellular pertussis, hepatitis B virus-inactivated poliovirus and Haemophilus influenzae type b vaccine
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

Arm title	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™

Arm description:

Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A co-administered with Infanrix™ IPV Hib and Baxter's Men-C conjugate vaccine (NeisVac-C™) received a booster dose of the GSK1024850A vaccine co-administered with GSK Biologicals' DTPa-combined vaccine (either Infanrix™ hexa in Germany and Poland or Infanrix™ IPV Hib in Spain) Hib and NeisVac-C™ at 11-18 months of age. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ hexa and Infanrix™ IPV Hib vaccines were administered in the upper left thigh or deltoid; and NeisVac-C™ was administered in the lower left thigh or deltoid.

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

Dosage and administration details:

One dose of the vaccine was administered in the right thigh or deltoid.

Investigational medicinal product name	Infanrix IPV + Hib
Investigational medicinal product code	
Other name	DTPa- IPV/Hib, Infanrix IPV Hib, GSK Biologicals' diphtheria-tetanus-acellular pertussis-inactivated poliovirus and Haemophilus influenzae type b vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

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.

Investigational medicinal product name	Infanrix Hexa
Investigational medicinal product code	
Other name	DTPa-IPV-HBV / Hib, GSK Biologicals' diphtheria-tetanus-acellular pertussis, hepatitis B virus-inactivated poliovirus and Haemophilus influenzae type b vaccine
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

Arm title	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™

Arm description:

This group is also referred to as the Group 10Pn + Hib-MenC in this record. Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A co-administered with Infanrix™ penta and GSK Biologicals' combined Hib-MenC vaccine (Menitorix™) received a booster dose of the GSK1024850A vaccine co-administered with DTPa-combined vaccine (either Infanrix™ penta in Germany and Poland or Infanrix™ IPV in Spain) and Menitorix™ at 11-18 months of age. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ penta and Infanrix™ IPV vaccines were administered in the upper left thigh or deltoid; and Menitorix™ was administered in the lower left thigh or deltoid.

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

Dosage and administration details:

One dose of the vaccine was administered in the right thigh or deltoid.

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:

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

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 solution for solution 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.

Investigational medicinal product name	Infanrix IPV
Investigational medicinal product code	
Other name	DTPa- IPV, Infanrix™ IPV, GSK Biologicals' diphtheria-tetanus-acellular pertussis-inactivated poliovirus vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

Arm title	Prevenar™ + Menitorix™

Arm description:

This group is also referred to as the Group Prevenar in this record. Subjects previously vaccinated with a 3-dose course of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and GSK Biologicals' combined Hib-MenC vaccine (Menitorix™) received a booster dose of Prevenar™ co-administered with DTPa-combined vaccine (either Infanrix™ penta in Germany and Poland or Infanrix™ IPV in Spain) and Menitorix™ at 11-18 months of age. The 7Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ penta and Infanrix™ IPV vaccines were administered in the upper left thigh or deltoid; and Menitorix™ was administered in the lower left thigh or deltoid.

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:

One dose of the vaccine was administered in the right thigh or deltoid.

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:

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

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 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.

Investigational medicinal product name	Infanrix IPV
Investigational medicinal product code	
Other name	DTPa- IPV, GSK Biologicals' diphtheria-tetanus-acellular pertussis-inactivated poliovirus vaccine
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

Number of subjects in period 1	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™
Started	359	363	358
Completed	355	352	352
Not completed	4	11	6
Consent withdrawn by subject	-	-	-
Lost to follow-up	4	11	6

Number of subjects in period 1	Prevenar™ + Menitorix™
Started	357
Completed	350
Not completed	7
Consent withdrawn by subject	1
Lost to follow-up	6

Baseline characteristics

Reporting groups	
Reporting group title	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™

Reporting group description:

Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (10Pn) co-administered with Infanrix™ IPV Hib and Wyeth's Men-C conjugate vaccine (Meningitec™) received a booster dose of the 10Pn vaccine co-administered with GSK Biologicals' DTPa-combined vaccine (either Infanrix™ hexa in Germany and Poland or Infanrix™ IPV Hib in Spain) and Meningitec™ at 11-18 months of age. All vaccines were administered intramuscularly in the thigh for children aged <12 months or in the thigh or deltoid for children aged ≥ 12 months. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ hexa and Infanrix™ IPV Hib vaccines were administered in the upper left thigh or deltoid; and Meningitec™ was administered in the lower left thigh or deltoid.

Reporting group title	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™

Reporting group description:

Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A co-administered with Infanrix™ IPV Hib and Baxter's Men-C conjugate vaccine (NeisVac-C™) received a booster dose of the GSK1024850A vaccine co-administered with GSK Biologicals' DTPa-combined vaccine (either Infanrix™ hexa in Germany and Poland or Infanrix™ IPV Hib in Spain) Hib and NeisVac-C™ at 11-18 months of age. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ hexa and Infanrix™ IPV Hib vaccines were administered in the upper left thigh or deltoid; and NeisVac-C™ was administered in the lower left thigh or deltoid.

Reporting group title	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™

Reporting group description:

This group is also referred to as the Group 10Pn + Hib-MenC in this record. Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A co-administered with Infanrix™ penta and GSK Biologicals' combined Hib-MenC vaccine (Menitorix™) received a booster dose of the GSK1024850A vaccine co-administered with DTPa-combined vaccine (either Infanrix™ penta in Germany and Poland or Infanrix™ IPV in Spain) and Menitorix™ at 11-18 months of age. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ penta and Infanrix™ IPV vaccines were administered in the upper left thigh or deltoid; and Menitorix™ was administered in the lower left thigh or deltoid.

Reporting group title	Prevenar™ + Menitorix™

Reporting group description:

This group is also referred to as the Group Prevenar in this record. Subjects previously vaccinated with a 3-dose course of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and GSK Biologicals' combined Hib-MenC vaccine (Menitorix™) received a booster dose of Prevenar™ co-administered with DTPa-combined vaccine (either Infanrix™ penta in Germany and Poland or Infanrix™ IPV in Spain) and Menitorix™ at 11-18 months of age. The 7Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ penta and Infanrix™ IPV vaccines were administered in the upper left thigh or deltoid; and Menitorix™ was administered in the lower left thigh or deltoid.

Reporting group values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™
Number of subjects	359	363	358
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	359	363	358
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: months			
arithmetic mean	14.3	14.3	14.3
standard deviation	± 1.81	± 1.74	± 1.78
Gender categorical			
Units: Subjects			
Female	182	176	195
Male	177	187	163

Reporting group values	Prevenar™ + Menitorix™	Total	
Number of subjects	357	1437	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	357	1437	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	0	0	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: months			
arithmetic mean	14.3		
standard deviation	± 1.78	-	
Gender categorical			
Units: Subjects			
Female	171	724	
Male	186	713	

End points

End points reporting groups

Reporting group title	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™

Reporting group description:

Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A (10Pn) co-administered with Infanrix™ IPV Hib and Wyeth's Men-C conjugate vaccine (Meningitec™) received a booster dose of the 10Pn vaccine co-administered with GSK Biologicals' DTPa-combined vaccine (either Infanrix™ hexa in Germany and Poland or Infanrix™ IPV Hib in Spain) and Meningitec™ at 11-18 months of age. All vaccines were administered intramuscularly in the thigh for children aged <12 months or in the thigh or deltoid for children aged ≥ 12 months. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ hexa and Infanrix™ IPV Hib vaccines were administered in the upper left thigh or deltoid; and Meningitec™ was administered in the lower left thigh or deltoid.

Reporting group title	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™

Reporting group description:

Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A co-administered with Infanrix™ IPV Hib and Baxter's Men-C conjugate vaccine (NeisVac-C™) received a booster dose of the GSK1024850A vaccine co-administered with GSK Biologicals' DTPa-combined vaccine (either Infanrix™ hexa in Germany and Poland or Infanrix™ IPV Hib in Spain) Hib and NeisVac-C™ at 11-18 months of age. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ hexa and Infanrix™ IPV Hib vaccines were administered in the upper left thigh or deltoid; and NeisVac-C™ was administered in the lower left thigh or deltoid.

Reporting group title	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™

Reporting group description:

This group is also referred to as the Group 10Pn + Hib-MenC in this record. Subjects previously vaccinated with a 3-dose course of GSK Biologicals' pneumococcal conjugate vaccine GSK1024850A co-administered with Infanrix™ penta and GSK Biologicals' combined Hib-MenC vaccine (Menitorix™) received a booster dose of the GSK1024850A vaccine co-administered with DTPa-combined vaccine (either Infanrix™ penta in Germany and Poland or Infanrix™ IPV in Spain) and Menitorix™ at 11-18 months of age. The 10Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ penta and Infanrix™ IPV vaccines were administered in the upper left thigh or deltoid; and Menitorix™ was administered in the lower left thigh or deltoid.

Reporting group title	Prevenar™ + Menitorix™

Reporting group description:

This group is also referred to as the Group Prevenar in this record. Subjects previously vaccinated with a 3-dose course of Wyeth's 7-valent pneumococcal conjugate vaccine (Prevenar™ or 7Pn) co-administered with Infanrix™ penta and GSK Biologicals' combined Hib-MenC vaccine (Menitorix™) received a booster dose of Prevenar™ co-administered with DTPa-combined vaccine (either Infanrix™ penta in Germany and Poland or Infanrix™ IPV in Spain) and Menitorix™ at 11-18 months of age. The 7Pn vaccine was administered in the right thigh or deltoid; the Infanrix™ penta and Infanrix™ IPV vaccines were administered in the upper left thigh or deltoid; and Menitorix™ was administered in the lower left thigh or deltoid.

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.

End point type	Primary

End point timeframe:

During the 4-day (Day 0-3) period after the booster vaccination

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: This endpoint is related to assess solely the difference between the GSK's 10-valent Pneumococcal vaccine 1024850A + Menitorix™ and Prevenar™ + Menitorix™ groups as regards incidence of Grade 3 fever.

End point values	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	355	355		
Units: subjects				
> 39.0 degrees Celsius	11	8		

Statistical analyses

Statistical analysis title	Non-inferiority of 10Pn vs 7Pn vaccine

Statistical analysis description:

Analysis assessed the difference in percentage of subjects reporting Grade 3 fever (rectal temperature > 39.0°C). Non-inferiority was supported if one could rule out an increase in terms of percentage of subjects with Grade 3 fever (GSK's 10-valent Pneumococcal vaccine 1024850A + Menitorix™ group minus Prevenar™ + Menitorix™ control group) above the clinically acceptable limit of 5% + half the incidence in control (= null hypothesis) as shown by an one-sided P-value < 2.5%.

Comparison groups	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™ v Prevenar™ + Menitorix™
Number of subjects included in analysis	710
Analysis specification	Pre-specified
Analysis type	non-inferiority
P-value	< 0.001 [2]
Method	Kem Phillip's statistical test
Parameter estimate	Difference in percentage
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.67
upper limit	3.48

Notes:

[2] - Non-inferiority was evaluated via the calculation of p-value using Kem Phillip's statistical test method, an extension of Farrington and Manning's methods. This allowed the inferiority limit to vary taking into account the underlying failure rates.

Secondary: Number of subjects reporting solicited local symptoms

End point title	Number of subjects reporting solicited local symptoms

End point description:

Solicited local symptoms assessed include pain, redness and swelling.

End point type	Secondary

End point timeframe:

During the 4-day (Day 0-3) period after the booster vaccination

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	356	357	355	355
Units: subjects				
Pain	196	195	193	165
Redness	194	183	186	173
Swelling	162	148	150	134

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting solicited general symptoms

End point title	Number of subjects reporting solicited general symptoms

End point description:

Solicited general symptoms assessed include drowsiness, fever, irritability, and loss of appetite.

End point type	Secondary

End point timeframe:

During the 4-day (Day 0-3) period after the booster vaccination

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	356	357	355	355
Units: subjects				
Drowsiness	124	142	139	105
Fever (≥ 38.0 °C)	109	122	105	108
Irritability	170	190	191	157
Loss of appetite	101	99	112	93

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting unsolicited adverse events (AE)

End point title	Number of subjects reporting unsolicited adverse events (AE)

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.

End point type	Secondary

End point timeframe:

During the 31-day (Day 0-30) period after the booster vaccination

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	359	363	358	357
Units: subjects				
Number of subjects reporting unsolicited AEs	59	74	59	76

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting serious adverse events (SAE)

End point title	Number of subjects reporting serious adverse events (SAE)

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, is a congenital anomaly/birth defect in the offspring of a study subject, or may evolve into one of the outcomes listed above.

End point type	Secondary

End point timeframe:

During the 31-day (Day 0-30) period after the booster vaccination

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	359	363	358	357
Units: subjects				
Number of subjects reporting SAEs	3	5	3	2

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects reporting serious adverse events (SAE)

End point title	Number of subjects reporting serious adverse events (SAE)

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, is a congenital anomaly/birth defect in the offspring of a study subject, or may evolve into one of the outcomes listed above.

End point type	Secondary

End point timeframe:

From the beginning of the study up to the end of the extended 6-month safety follow-up period

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	359	363	358	357
Units: subjects				
Number of subjects reporting SAEs	15	9	13	13

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with vaccine pneumococcal serotype antibody concentrations above the cut-off value

End point title	Number of subjects with vaccine pneumococcal serotype antibody concentrations above the cut-off value

End point description:

Anti-pneumococcal antibody concentration cut-off value assessed was 0.05 microgram per milliliter (µg/mL). The vaccine pneumococcal serotypes assessed include 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, and 23F.

End point type	Secondary

End point timeframe:

Before (pre) and one month after (post) the booster administration

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	158	158	160	153
Units: subjects				
Anti-1 pre (N=150,152,149, 151)	146	146	140	21
Anti-1 post (N=158,152,160,151)	158	152	160	28
Anti-4 pre (N=153,156,150,153)	152	156	147	150
Anti-4 post (N=158,153,160,152)	158	153	160	152
Anti-5 pre (N=149,146,146,148)	149	146	144	37
Anti-5 post (N=157,153,160,150)	157	153	160	64
Anti-6B pre (N=151,155,150,151)	149	153	144	137
Anti-6B post (N=158,153,160,153)	157	151	158	153
Anti-7F pre (N=149,153,148,151)	149	153	147	18
Anti-7F post (N=158,152,160,151)	158	152	160	25
Anti-9V pre (N=149,155,149,152)	149	154	149	152
Anti-9V post (N=158,153,160,153)	158	152	160	153
Anti-14 pre (N=153,158,152,153)	151	157	152	151
Anti-14 post (N=158,153,160,153)	158	153	160	153
Anti-18C pre (N=151,153,145,151)	149	151	145	151
Anti-18C post (N=157,152,160,152)	157	152	160	152
Anti-19F pre (N=143,146,139,150)	143	146	139	143
Anti-19F post (N=158,151,160,152)	158	151	160	152
Anti-23F pre (N=152,156,150,153)	149	153	144	141
Anti-23F post (N=158,153,160,153)	158	152	158	153

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with opsonophagocytic activity against vaccine pneumococcal serotypes above the cut-off value

End point title	Number of subjects with opsonophagocytic activity against vaccine pneumococcal serotypes above the cut-off value

End point description:

Cut-off value for opsonophagocytic activity against pneumococcal antibody assessed was ≥ 8. The vaccine pneumococcal serotypes assessed include 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F, 23F.

End point type	Secondary

End point timeframe:

Before (pre) and one month after (post) the booster administration

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	145	145	146	143
Units: subjects				
Opsono-1 pre (N=144,145,141,143)	46	39	41	8
Opsono-1 post (N=140,139,140,137)	132	133	127	12
Opsono-4 pre (N=104,121,112,109)	61	67	61	73
Opsono-4 post (N=137,134,140,135)	137	134	140	135
Opsono-5 pre (N=116,114,117,124)	77	71	72	3
Opsono-5 post (N=124,130,136,127)	121	127	131	4
Opsono-6B pre (N=133,132,133,137)	75	60	75	67
Opsono-6B post (N=142,135,142,140)	134	127	135	138
Opsono-7F pre (N=111,122,115,104)	109	117	109	42
Opsono-7F post (N=140,137,139,112)	140	137	139	53
Opsono-9V pre (N=133,133,130,130)	131	130	122	126
Opsono-9V post (N=143,139,143,137)	143	139	143	137
Opsono-14 pre (N=121,125,114,125)	115	116	107	124
Opsono-14 post (N=137,138,138,134)	137	138	138	134
Opsono-18C pre (N=126,118,123,123)	45	54	34	35
Opsono-18C post (N=121,129,121,114)	121	127	121	110
Opsono-19F pre (N=127,135,134,134)	102	110	95	29
Opsono-19F post (N=137,137,139,133)	133	132	139	131
Opsono-23F pre (N=132,136,128,137)	121	120	105	124
Opsono-23F post (N=145,143,146,143)	145	143	146	143

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with cross-reactive pneumococcal serotype antibody concentrations above the cut-off value

End point title	Number of subjects with cross-reactive pneumococcal serotype antibody concentrations above the cut-off value

End point description:

Anti-pneumococcal antibody cut-off value assessed was 0.05 microgram per milliliter (µg/mL). The cross-reactive pneumococcal serotypes assessed include 6A and 19A.

End point type	Secondary

End point timeframe:

Before (pre) and one month after (post) the booster administration

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	157	153	160	152
Units: subjects				
Anti-6A pre (N=145,144,144,149)	126	120	119	110
Anti-6A post (N=156,152,159,152)	152	145	149	148
Anti-19A pre (N=145,153,145,151)	130	138	121	87
Anti-19A post (N=157,153,160,152)	154	151	155	149

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with opsonophagocytic activity against cross-reactive pneumococcal serotypes above the cut-off value

End point title	Number of subjects with opsonophagocytic activity against cross-reactive pneumococcal serotypes above the cut-off value

End point description:

Anti-pneumococcal antibody cut-off value assessed was ≥ 8. The cross-reactive pneumococcal serotypes assessed include 6A and 19A.

End point type	Secondary

End point timeframe:

Before (pre) and one month after (post) the booster administration

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	133	138	136	134
Units: subjects				
Opsono-6A pre (N=108,110,106,110)	68	66	73	62
Opsono-6A post (N=127,128,128,122)	116	119	117	119
Opsono-19A pre (N=133,138,136,134)	4	11	4	2
Opsono-19A post (N=124,132,130,123)	77	75	50	29

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-protein D antibody concentrations above the cut-off value

End point title	Number of subjects with anti-protein D antibody concentrations above the cut-off value

End point description:

Anti-protein D antibody cut-off value assessed was ≥ 100 Enzyme-Linked Immuno Sorbent Assay (ELISA) unit per milliliter (EL.U/mL).

End point type	Secondary

End point timeframe:

Before (pre) and one month after (post) the booster administration

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	158	153	160	148
Units: subjects				
Pre (N=147,153,147,146)	144	147	138	59
Post (N=158,152,160,148)	158	151	160	66

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with meningococcal serogroup C serum bactericidal assay titer above the cut-off value

End point title	Number of subjects with meningococcal serogroup C serum bactericidal assay titer above the cut-off value

End point description:

Meningococcal serogroup C serum bactericidal assay titer cut-off value assessed was ≥ 8.

End point type	Secondary

End point timeframe:

Before (pre) and one month after (post) the booster administration

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	89	84	79	78
Units: subjects				
Pre (N=68,65,66,78)	57	62	62	68

Post (N=89,84,79,76)	89	84	79	76

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-meningococcal polysaccharide C antibody concentrations above the cut-off value

End point title	Number of subjects with anti-meningococcal polysaccharide C antibody concentrations above the cut-off value
End point description:	
Anti-meningococcal polysaccharide C antibody cut-off value assessed was ≥ 0.3 µg/mL.	
End point type	Secondary
End point timeframe:	
Before (pre) and one month after (post) the booster administration	

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	156	149	159	149
Units: subjects				
Pre (N=126,124,125,135)	95	82	105	102
Post (N=156,149,159,149)	156	149	159	149

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with anti-polyribosyl-ribitol phosphate antibody concentrations above the cut-off value

End point title	Number of subjects with anti-polyribosyl-ribitol phosphate antibody concentrations above the cut-off value
End point description:	
Anti-polyribosyl-ribitol phosphate antibody cut-off value assessed was ≥ 0.15 µg/mL.	
End point type	Secondary
End point timeframe:	
Before (pre) and one month after (post) the booster administration	

End point values	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™	Prevenar™ + Menitorix™
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	157	153	160	152
Units: subjects				
Pre (N=147,144,150,148)	122	128	145	143
Post (N=157,153,160,152)	157	153	160	152

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious adverse events were assessed during the entire study period. Systematically assessed frequent AEs were assessed during the 31-day post vaccination period. Solicited local/general symptoms were assessed during the 4-day post vaccination period.

Adverse event reporting additional description:

The occurrence of reported AEs (all/related) was not available and is encoded as equal to the number of subjects affected.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	9.0

Reporting groups

Reporting group title	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™

Reporting group description:

Subjects receiving a booster dose of pneumococcal conjugate vaccine GSK1024850A co-administered with GSK Biologicals' DTPa-combined vaccine (Infanrix™ hexa in Germany & Poland and Infanrix™ IPV Hib in Spain) and Wyeth's Men-C conjugate vaccine (Meningitec™) at 11-18 months of age.

Reporting group title	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™

Reporting group description:

Subjects receiving a booster dose of pneumococcal conjugate vaccine GSK1024850A co-administered with GSK Biologicals' DTPa-combined vaccine (Infanrix™ hexa in Germany & Poland and Infanrix™ IPV Hib in Spain) and Baxter's Men-C conjugate vaccine (NeisVac-C™) at 11-18 months of age.

Reporting group title	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™

Reporting group description:

Subjects receiving a booster dose of pneumococcal conjugate vaccine GSK1024850A co-administered with DTPa-combined vaccine (Infanrix™ penta in Germany & Poland and Infanrix™ IPV in Spain) and GSK Biologicals' combined Hib-MenC vaccine (Menitorix™) at 11-18 months of age.

Reporting group title	Prevenar™ + Menitorix™

Reporting group description:

Subjects receiving a booster dose of Wyeth's pneumococcal conjugate vaccine (Prevenar™) co-administered with DTPa-combined vaccine (Infanrix™ penta in Germany & Poland and Infanrix™ IPV in Spain) and GSK Biologicals' combined Hib-MenC vaccine (Menitorix™) at 11-18 months of age.

Serious adverse events	GSK's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 359 (4.18%)	9 / 363 (2.48%)	13 / 358 (3.63%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Thermal burn			

subjects affected / exposed	2 / 359 (0.56%)	0 / 363 (0.00%)	1 / 358 (0.28%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	0 / 358 (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
Electric shock			
subjects affected / exposed	1 / 359 (0.28%)	0 / 363 (0.00%)	0 / 358 (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
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 359 (0.00%)	1 / 363 (0.28%)	2 / 358 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	1 / 358 (0.28%)
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			
Gastroenteritis rotavirus			
subjects affected / exposed	4 / 359 (1.11%)	0 / 363 (0.00%)	1 / 358 (0.28%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	0 / 358 (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
Gastritis			
subjects affected / exposed	1 / 359 (0.28%)	1 / 363 (0.28%)	0 / 358 (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
Respiratory, thoracic and mediastinal			

disorders			
Bronchpneumopathy			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	1 / 358 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchospasm			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	1 / 358 (0.28%)
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 failure			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	1 / 358 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
subjects affected / exposed	0 / 359 (0.00%)	1 / 363 (0.28%)	0 / 358 (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
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	1 / 358 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	1 / 358 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	2 / 359 (0.56%)	4 / 363 (1.10%)	2 / 358 (0.56%)
occurrences causally related to treatment / all	0 / 2	0 / 4	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	2 / 359 (0.56%)	1 / 363 (0.28%)	0 / 358 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	1 / 359 (0.28%)	1 / 363 (0.28%)	0 / 358 (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
Bronchitis			
subjects affected / exposed	1 / 359 (0.28%)	0 / 363 (0.00%)	1 / 358 (0.28%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngitis			
subjects affected / exposed	0 / 359 (0.00%)	1 / 363 (0.28%)	2 / 358 (0.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute tonsillitis			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	1 / 358 (0.28%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Laryngitis			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	0 / 358 (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
Pyelonephritis acute			
subjects affected / exposed	0 / 359 (0.00%)	0 / 363 (0.00%)	0 / 358 (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
Salmonellosis			
subjects affected / exposed	1 / 359 (0.28%)	0 / 363 (0.00%)	0 / 358 (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
Tracheitis			

subjects affected / exposed	1 / 359 (0.28%)	0 / 363 (0.00%)	0 / 358 (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 / 359 (0.00%)	1 / 363 (0.28%)	0 / 358 (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
Viral infection			
subjects affected / exposed	0 / 359 (0.00%)	1 / 363 (0.28%)	0 / 358 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 359 (0.28%)	0 / 363 (0.00%)	0 / 358 (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™		
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 357 (3.64%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Concussion			
subjects affected / exposed	1 / 357 (0.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Electric shock			

subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	2 / 357 (0.56%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Epilepsy			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	2 / 357 (0.56%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchpneumopathy			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bronchospasm			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Respiratory failure			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Wheezing			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Breath holding			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	3 / 357 (0.84%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	3 / 357 (0.84%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Bronchopneumonia			
subjects affected / exposed	2 / 357 (0.56%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Bronchitis			

subjects affected / exposed	1 / 357 (0.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pharyngitis			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute tonsillitis			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Laryngitis			
subjects affected / exposed	1 / 357 (0.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyelonephritis acute			
subjects affected / exposed	1 / 357 (0.28%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Salmonellosis			
subjects affected / exposed	0 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tracheitis			
subjects affected / exposed	0 / 357 (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 / 357 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Viral infection			

subjects affected / exposed	0 / 357 (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	0 / 357 (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's 10-valent Pneumococcal vaccine 1024850A + Meningitec™	GSK's 10-valent Pneumococcal Vaccine 1024850A + NeisVac-C™	GSK's 10-valent Pneumococcal Vaccine 1024850A + Menitorix™
Total subjects affected by non-serious adverse events			
subjects affected / exposed	196 / 359 (54.60%)	195 / 363 (53.72%)	193 / 358 (53.91%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	196 / 359 (54.60%)	195 / 363 (53.72%)	193 / 358 (53.91%)
occurrences (all)	196	195	193
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	194 / 359 (54.04%)	183 / 363 (50.41%)	186 / 358 (51.96%)
occurrences (all)	194	183	186
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	162 / 359 (45.13%)	148 / 363 (40.77%)	150 / 358 (41.90%)
occurrences (all)	162	148	150
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	124 / 359 (34.54%)	142 / 363 (39.12%)	139 / 358 (38.83%)
occurrences (all)	124	142	139
Fever			
alternative assessment type: Systematic			

subjects affected / exposed	109 / 359 (30.36%)	122 / 363 (33.61%)	105 / 358 (29.33%)
occurrences (all)	109	122	105
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	170 / 359 (47.35%)	190 / 363 (52.34%)	191 / 358 (53.35%)
occurrences (all)	170	190	191
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed	101 / 359 (28.13%)	99 / 363 (27.27%)	112 / 358 (31.28%)
occurrences (all)	101	99	112
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	6 / 359 (1.67%)	19 / 363 (5.23%)	14 / 358 (3.91%)
occurrences (all)	6	19	14

Non-serious adverse events	Prevenar™ + Menitorix™		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	173 / 357 (48.46%)		
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	165 / 357 (46.22%)		
occurrences (all)	165		
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	173 / 357 (48.46%)		
occurrences (all)	173		
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	134 / 357 (37.54%)		
occurrences (all)	134		
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	105 / 357 (29.41%)		
occurrences (all)	105		

Fever			
alternative assessment type: Systematic			
subjects affected / exposed	108 / 357 (30.25%)		
occurrences (all)	108		
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	157 / 357 (43.98%)		
occurrences (all)	157		
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed	93 / 357 (26.05%)		
occurrences (all)	93		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	18 / 357 (5.04%)		
occurrences (all)	18		

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