



Clinical trial results:

A phase III, open, controlled study to evaluate the immunogenicity, safety and reactogenicity of GSK Biologicals' 10- valent pneumococcal conjugate vaccine administered to children with sickle cell disease between 8 weeks and 2 years of age, as compared to healthy children.

Summary

EudraCT number	2012-000254-64
Trial protocol	Outside EU/EEA
Global end of trial date	23 May 2013

Results information

Result version number	v1
This version publication date	01 March 2016
First version publication date	25 July 2015

Trial information

Trial identification

Sponsor protocol code	114056
-----------------------	--------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01175083
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, 44 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 44 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-000673-PIP01-09
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	01 June 2011
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	23 May 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the immunogenicity of GSK Biologicals' 10-valent pneumococcal conjugate vaccine when co-administered with DTPw-HBV/Hib and OPV vaccines in children with sickle cell disease, one month after completion of the 3-dose primary vaccination course before 6 months of age

Protection of trial subjects:

All subjects were supervised after vaccination/product administration with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 June 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Burkina Faso: 300
Worldwide total number of subjects	300
EEA total number of subjects	0

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)	300
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:

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

Period 1

Period 1 title	Overall study (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	<6S Group

Arm description:

Children below 6 months of age with sickle cell disease, receiving a 3-dose primary vaccination with 10Pn-PD-DiT vaccine at approximately 8-12-16 weeks of age and booster vaccination at 9-10 months of age. Subjects received DTPw-HBV/Hib + OPV as co-administered vaccines. The allowable intervals between the primary vaccination doses were 28-42 days.

Arm type	Experimental
Investigational medicinal product name	GSK1024850A (Synflorix™)
Investigational medicinal product code	
Other name	GSK Biologicals' 10-valent pneumococcal polysaccharide and non-typeable Haemophilus influenzae (H. influenzae) protein D conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 intramuscular vaccine doses were administered intramuscularly into the right thigh.

Investigational medicinal product name	Tritanrix-HepB/Hib
Investigational medicinal product code	
Other name	DTPw-HBV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, 4 doses in the left thigh.

Investigational medicinal product name	Polio Sabin
Investigational medicinal product code	
Other name	OPV
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

4 doses administered orally.

Arm title	<6NS Group
------------------	------------

Arm description:

Healthy children below 6 months of age, receiving a 3-dose primary vaccination with 10Pn-PD-DiT vaccine at approximately 8-12-16 weeks of age and booster vaccination at 9-10 months of age. Subjects received DTPw-HBV/Hib + OPV as co-administered vaccines. The allowable intervals between

the primary vaccination doses were 28-42 days.

Arm type	Active comparator
Investigational medicinal product name	GSK1024850A (Synflorix™)
Investigational medicinal product code	
Other name	GSK Biologicals' 10-valent pneumococcal polysaccharide and non-typeable Haemophilus influenzae (H. influenzae) protein D conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 intramuscular vaccine doses were administered intramuscularly into the right thigh.

Investigational medicinal product name	Tritanrix-HepB/Hib
Investigational medicinal product code	
Other name	DTPw-HBV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Intramuscular injection, 4 doses in the left thigh.

Investigational medicinal product name	Polio Sabin
Investigational medicinal product code	
Other name	OPV
Pharmaceutical forms	Oral drops
Routes of administration	Oral use

Dosage and administration details:

4 doses administered orally.

Arm title	7-11S Group
------------------	-------------

Arm description:

Children between 7-11 months of age with sickle cell disease, receiving a 2-dose primary vaccination with 10Pn-PD-DiT vaccine starting at 7-11 months of age with an interval of at least 4 weeks (28-42 days) between primary doses. Subjects received a booster after an interval of 2 to 4 months since the previous dose.

Arm type	Experimental
Investigational medicinal product name	GSK1024850A (Synflorix™)
Investigational medicinal product code	
Other name	GSK Biologicals' 10-valent pneumococcal polysaccharide and non-typeable Haemophilus influenzae (H. influenzae) protein D conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 intramuscular vaccine doses were administered intramuscularly into the right thigh.

Arm title	7-11NS Group
------------------	--------------

Arm description:

Healthy children between 7-11 months of age, receiving a 2-dose primary vaccination with 10Pn-PD-DiT vaccine starting at 7-11 months of age with an interval of at least 4 weeks (28-42 days) between primary doses. Subjects received a booster after an interval of 2 to 4 months since the previous dose.

Arm type	Active comparator
Investigational medicinal product name	GSK1024850A (Synflorix™)
Investigational medicinal product code	
Other name	GSK Biologicals' 10-valent pneumococcal polysaccharide and non-typeable Haemophilus influenzae (H. influenzae) protein D conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 intramuscular vaccine doses were administered intramuscularly into the right thigh.

Arm title	12-23S Group
Arm description: Children between 12-23 months of age with sickle cell disease, receiving a 2-dose vaccination with 10Pn-PD-DiT vaccine starting at 12-23 months of age with an interval of 2 to 4 months between doses.	
Arm type	Experimental
Investigational medicinal product name	GSK1024850A (Synflorix™)
Investigational medicinal product code	
Other name	GSK Biologicals' 10-valent pneumococcal polysaccharide and non-typeable Haemophilus influenzae (H. influenzae) protein D conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 intramuscular vaccine doses were administered intramuscularly into the right thigh.

Arm title	12-23NS Group
Arm description: Healthy children between 12-23 months of age, receiving a 2-dose vaccination with 10Pn-PD-DiT vaccine starting at 12-23 months of age with an interval of 2 to 4 months between doses.	
Arm type	Active comparator
Investigational medicinal product name	GSK1024850A (Synflorix™)
Investigational medicinal product code	
Other name	GSK Biologicals' 10-valent pneumococcal polysaccharide and non-typeable Haemophilus influenzae (H. influenzae) protein D conjugate vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 intramuscular vaccine doses were administered intramuscularly into the right thigh.

Number of subjects in period 1	<6S Group	<6NS Group	7-11S Group
Started	50	50	50
Completed	49	49	49
Not completed	1	1	1
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	-	-	-
Not coming back for booster vaccination	1	1	-
Lost to follow-up	-	-	-

Number of subjects in period 1	7-11NS Group	12-23S Group	12-23NS Group
Started	50	50	50
Completed	49	50	47
Not completed	1	0	3

Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	1	-	2
Not coming back for booster vaccination	-	-	-
Lost to follow-up	-	-	1

Baseline characteristics

Reporting groups

Reporting group title	<6S Group
Reporting group description: Children below 6 months of age with sickle cell disease, receiving a 3-dose primary vaccination with 10Pn-PD-DiT vaccine at approximately 8-12-16 weeks of age and booster vaccination at 9-10 months of age. Subjects received DTPw-HBV/Hib + OPV as co-administered vaccines. The allowable intervals between the primary vaccination doses were 28-42 days.	
Reporting group title	<6NS Group
Reporting group description: Healthy children below 6 months of age, receiving a 3-dose primary vaccination with 10Pn-PD-DiT vaccine at approximately 8-12-16 weeks of age and booster vaccination at 9-10 months of age. Subjects received DTPw-HBV/Hib + OPV as co-administered vaccines. The allowable intervals between the primary vaccination doses were 28-42 days.	
Reporting group title	7-11S Group
Reporting group description: Children between 7-11 months of age with sickle cell disease, receiving a 2-dose primary vaccination with 10Pn-PD-DiT vaccine starting at 7-11 months of age with an interval of at least 4 weeks (28-42 days) between primary doses. Subjects received a booster after an interval of 2 to 4 months since the previous dose.	
Reporting group title	7-11NS Group
Reporting group description: Healthy children between 7-11 months of age, receiving a 2-dose primary vaccination with 10Pn-PD-DiT vaccine starting at 7-11 months of age with an interval of at least 4 weeks (28-42 days) between primary doses. Subjects received a booster after an interval of 2 to 4 months since the previous dose.	
Reporting group title	12-23S Group
Reporting group description: Children between 12-23 months of age with sickle cell disease, receiving a 2-dose vaccination with 10Pn-PD-DiT vaccine starting at 12-23 months of age with an interval of 2 to 4 months between doses.	
Reporting group title	12-23NS Group
Reporting group description: Healthy children between 12-23 months of age, receiving a 2-dose vaccination with 10Pn-PD-DiT vaccine starting at 12-23 months of age with an interval of 2 to 4 months between doses.	

Reporting group values	<6S Group	<6NS Group	7-11S Group
Number of subjects	50	50	50
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 standard deviation	8.4 ± 0.95	8.6 ± 0.85	8.6 ± 1.52
Gender categorical Units: Subjects			
Female	21	29	26
Male	29	21	24

Reporting group values	7-11NS Group	12-23S Group	12-23NS Group
Number of subjects	50	50	50
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 standard deviation	8.3 ± 1.21	16.6 ± 3.27	16.7 ± 3.49
Gender categorical Units: Subjects			
Female	32	15	24
Male	18	35	26

Reporting group values	Total		
Number of subjects	300		
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	0 0 0 0 0 0 0 0 0		
Age continuous Units: weeks arithmetic mean standard deviation	-		

Gender categorical			
Units: Subjects			
Female	147		
Male	153		

End points

End points reporting groups

Reporting group title	<6S Group
Reporting group description: Children below 6 months of age with sickle cell disease, receiving a 3-dose primary vaccination with 10Pn-PD-DiT vaccine at approximately 8-12-16 weeks of age and booster vaccination at 9-10 months of age. Subjects received DTPw-HBV/Hib + OPV as co-administered vaccines. The allowable intervals between the primary vaccination doses were 28-42 days.	
Reporting group title	<6NS Group
Reporting group description: Healthy children below 6 months of age, receiving a 3-dose primary vaccination with 10Pn-PD-DiT vaccine at approximately 8-12-16 weeks of age and booster vaccination at 9-10 months of age. Subjects received DTPw-HBV/Hib + OPV as co-administered vaccines. The allowable intervals between the primary vaccination doses were 28-42 days.	
Reporting group title	7-11S Group
Reporting group description: Children between 7-11 months of age with sickle cell disease, receiving a 2-dose primary vaccination with 10Pn-PD-DiT vaccine starting at 7-11 months of age with an interval of at least 4 weeks (28-42 days) between primary doses. Subjects received a booster after an interval of 2 to 4 months since the previous dose.	
Reporting group title	7-11NS Group
Reporting group description: Healthy children between 7-11 months of age, receiving a 2-dose primary vaccination with 10Pn-PD-DiT vaccine starting at 7-11 months of age with an interval of at least 4 weeks (28-42 days) between primary doses. Subjects received a booster after an interval of 2 to 4 months since the previous dose.	
Reporting group title	12-23S Group
Reporting group description: Children between 12-23 months of age with sickle cell disease, receiving a 2-dose vaccination with 10Pn-PD-DiT vaccine starting at 12-23 months of age with an interval of 2 to 4 months between doses.	
Reporting group title	12-23NS Group
Reporting group description: Healthy children between 12-23 months of age, receiving a 2-dose vaccination with 10Pn-PD-DiT vaccine starting at 12-23 months of age with an interval of 2 to 4 months between doses.	

Primary: Concentrations of antibodies against vaccine pneumococcal serotypes

End point title	Concentrations of antibodies against vaccine pneumococcal serotypes ^{[1][2]}
End point description: This outcome was measured only in <6S and <6NS Groups. Note that at the time this record was posted, no immunogenicity results were available, so the primary and secondary immunogenicity outcomes remain blank. They will be updated as soon as results become available.	
End point type	Primary
End point timeframe: 1 month after primary vaccination	

Notes:

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

Justification: Results were computed separately for sets of groups in this study.

[2] - 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: Results were computed separately for sets of groups in this study.

End point values	<6S Group	<6NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	0 ^[3]	0 ^[4]		
Units: E.U/mL				
geometric mean (confidence interval 95%)	(to)	(to)		

Notes:

[3] - No results were available at the time of posting this record.

[4] - No results were available at the time of posting this record.

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any and Grade 3 solicited local symptoms. ^[5]
-----------------	--

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary
----------------	-----------

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following each dose.

Notes:

[5] - 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: Results were computed separately for sets of groups in this study.

End point values	<6S Group	<6NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Any Pain, Dose 1	8	12		
Grade 3 Pain, Dose 1	0	0		
Any Redness, Dose 1	0	0		
Grade 3 Redness, Dose 1	0	0		
Any Swelling, Dose 1	0	0		
Grade 3 Swelling, Dose 1	0	0		
Any Pain, Dose 2	7	7		
Grade 3 Pain, Dose 2	0	0		
Any Redness, Dose 2	0	0		
Grade 3 Redness, Dose 2	0	0		
Any Swelling, Dose 2	0	1		
Grade 3 Swelling, Dose 2	0	0		
Any Pain, Dose 3	4	6		
Grade 3 Pain, Dose 3	0	0		
Any Redness, Dose 3	0	0		
Grade 3 Redness, Dose 3	0	0		
Any Swelling, Dose 3	0	0		
Grade 3 Swelling, Dose 3	0	0		
Any Pain, Across	17	23		
Grade 3 Pain, Across	0	0		

Any Redness, Across	0	0		
Grade 3 Redness, Across	0	0		
Any Swelling, Across	0	1		
Grade 3 Swelling, Across	0	0		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any, Grade 3 and related solicited general symptoms. ^[6]
-----------------	---

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and fever [defined as rectal temperature equal to or above 38 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 40.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary
----------------	-----------

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following each dose.

Notes:

[6] - 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: Results were computed separately for sets of groups in this study.

End point values	<6S Group	<6NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Any Drowsiness, Dose 1	0	0		
Grade 3 Drowsiness, Dose 1	0	0		
Related Drowsiness, Dose 1	0	0		
Any Irritability, Dose 1	0	2		
Grade 3 Irritability, Dose 1	0	0		
Related Irritability, Dose 1	0	0		
Any Loss of appetite, Dose 1	0	0		
Grade 3 Loss of appetite, Dose 1	0	0		
Related Loss of appetite, Dose 1	0	0		
Any Fever, Dose 1	34	31		
Grade 3 Fever, Dose 1	0	0		
Related Fever, Dose 1	31	29		
Any Drowsiness, Dose 2	0	0		
Grade 2 Drowsiness, Dose 2	0	0		
Related Drowsiness, Dose 2	0	0		
Any Irritability, Dose 2	0	0		
Grade 3 Irritability, Dose 2	0	0		
Related Irritability, Dose 2	0	0		
Any Loss of appetite, Dose 2	0	0		
Grade 3 Loss of appetite, Dose 2	0	0		
Related Loss of appetite, Dose 2	0	0		

Any Fever, Dose 2	40	30		
Grade 3 Fever, Dose 2	0	0		
Related Fever, Dose 2	38	28		
Any Drowsiness, Dose 3	0	0		
Grade 3 Drowsiness, Dose 3	0	0		
Related Drowsiness, Dose 3	0	0		
Any Irritability, Dose 3	3	4		
Grade 3 Irritability, Dose 3	0	0		
Related Irritability, Dose 3	3	3		
Any Loss of appetite, Dose 3	0	1		
Grade 3 Loss of appetite, Dose 3	0	0		
Related Loss of appetite, Dose 3	0	0		
Any Fever, Dose 3	30	30		
Grade 3 Fever, Dose 3	0	0		
Related Fever, Dose 3	30	28		
Any Drowsiness, Across Doses	0	0		
Grade 3 Drowsiness, Across Doses	0	0		
Related Drowsiness, Across Doses	0	0		
Any Irritability, Across Doses	3	6		
Grade 3 Irritability, Across Doses	0	0		
Related Irritability, Across Doses	3	3		
Any Loss of appetite, Across Doses	0	1		
Grade 3 Loss of appetite, Across Doses	0	0		
Related Loss of appetite, Across Doses	0	0		
Any Fever, Across Doses	48	43		
Grade 3 Fever, Across Doses	0	0		
Related Fever, Across Doses	46	43		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any unsolicited adverse events
-----------------	--

End point description:

An unsolicited AE covers 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 and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

End point type	Secondary
----------------	-----------

End point timeframe:

Within 31 days (Days 0-30) post each vaccination.

Notes:

[7] - 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: Results were computed separately for sets of groups in this study.

End point values	<6S Group	<6NS Group	7-11S Group	7-11NS Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: Subjects				
Any AEs post primary vaccination [N=50,50,50,50]	37	34	32	37
Any AEs post-booster vaccination [N=49,49,50,50]	8	17	18	12

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:	
Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.	
End point type	Secondary
End point timeframe:	
During the entire study period.	

End point values	<6S Group	<6NS Group	7-11S Group	7-11NS Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	50
Units: Subjects				
Any SAEs	3	9	3	4

End point values	12-23S Group	12-23NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Any SAEs	2	2		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any unsolicited adverse events
-----------------	--

End point description:

An unsolicited AE covers 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 and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

End point type	Secondary
----------------	-----------

End point timeframe:

Within the 31-day (Days 0-30) post vaccination period.

Notes:

[8] - 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: Results were computed separately for sets of groups in this study.

End point values	12-23S Group	12-23NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Any AE(s)	23	25		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any and Grade 3 solicited local symptoms. ^[9]
-----------------	--

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary
----------------	-----------

End point timeframe:

During the 4-day (Days 0-3) post-booster vaccination period.

Notes:

[9] - 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: Results were computed separately for sets of groups in this study.

End point values	<6S Group	<6NS Group	7-11S Group	7-11NS Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	49	50	50
Units: Subjects				
Any Pain	11	6	3	0
Grade 3 Pain	0	0	0	0
Any Redness	0	0	0	0
Grade 3 Redness	0	0	0	0
Any Swelling	1	0	1	0
Grade 3 Swelling	0	0	0	0

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any and Grade 3 solicited local symptoms. ^[10]
-----------------	---

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary
----------------	-----------

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following each dose.

Notes:

[10] - 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: Results were computed separately for sets of groups in this study.

End point values	12-23S Group	12-23NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Any Pain, Dose 1 [N=50,50]	9	6		
Grade 3 Pain, Dose 1 [N=50,50]	0	0		
Any Redness, Dose 1 [N=50,50]	0	0		
Grade 3 Redness, Dose 1 [N=50,50]	0	0		
Any Swelling, Dose 1 [N=50,50]	1	1		
Grade 3 Swelling, Dose 1 [N=50,50]	0	0		
Any Pain, Dose 2 [N=50,48]	5	3		
Grade 3 Pain, Dose 2 [N=50,48]	0	0		
Any Redness, Dose 2 [N=50,48]	0	0		
Grade 3 Redness, Dose 2 [N=50,48]	0	0		
Any Swelling, Dose 2 [N=50,48]	0	0		
Grade 3 Swelling, Dose 2 [N=50,48]	0	0		
Any Pain, Across Doses [N=50,50]	13	9		
Grade 3 Pain, Across Doses [N=50,50]	0	0		
Any Redness, Across Doses [N=50,50]	0	0		
Grade 3 Redness, Across Doses [N=50,50]	0	0		
Any Swelling, Across Doses [N=50,50]	1	1		
Grade 3 Swelling, Across Doses [N=50,50]	0	0		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any, Grade 3 and related solicited general symptoms. ^[11]
-----------------	--

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and fever [defined as rectal temperature equal to or above 38 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 40.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary
----------------	-----------

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following each dose.

Notes:

[11] - 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: Results were computed separately for sets of groups in this study.

End point values	7-11S Group	7-11NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Any Drowsiness, Dose 1	0	1		
Grade 3 Drowsiness, Dose 1	0	0		
Related Drowsiness, Dose 1	0	1		
Any Irritability, Dose 1	0	0		
Grade 3 Irritability, Dose 1	0	0		
Related Irritability, Dose 1	0	0		
Any Loss of appetite, Dose 1	0	0		
Grade 3 Loss of appetite, Dose 1	0	0		
Related Loss of appetite, Dose 1	0	0		
Any Fever, Dose 1	22	26		
Grade 3 Fever, Dose 1	0	0		
Related Fever, Dose 1	19	22		
Any Drowsiness, Dose 2	0	0		
Grade 3 Drowsiness, Dose 2	0	0		
Related Drowsiness, Dose 2	0	0		
Any Irritability, Dose 2	0	0		
Grade 3 Irritability, Dose 2	0	0		
Related Irritability, Dose 2	0	0		
Any Loss of appetite, Dose 2	0	0		
Grade 3 Loss of appetite, Dose 2	0	0		
Related Loss of appetite, Dose 2	0	0		

Any Fever, Dose 2	22	11		
Grade 3 Fever, Dose 2	0	0		
Related Fever, Dose 2	20	9		
Any Drowsiness, Across Doses	0	1		
Grade 3 Drowsiness, Across Doses	0	0		
Related Drowsiness, Across Doses	0	1		
Any Irritability, Across Doses	0	0		
Grade 3 Irritability, Across Doses	0	0		
Related Irritability, Across Doses	0	0		
Any Loss of appetite, Across Doses	0	0		
Grade 3 Loss of appetite, Across Doses	0	0		
Related Loss of appetite, Across Doses	0	0		
Any Fever, Across Doses	31	29		
Grade 3 Fever, Across Doses	0	0		
Related Fever, Across Doses	29	25		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any, Grade 3 and related solicited general symptoms. ^[12]
-----------------	--

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and fever [defined as rectal temperature equal to or above 38 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 40.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary
----------------	-----------

End point timeframe:

During the 4-day (Days 0-3) post-booster vaccination period.

Notes:

[12] - 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: Results were computed separately for sets of groups in this study.

End point values	<6S Group	<6NS Group	7-11S Group	7-11NS Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	49	49	50	50
Units: Subjects				
Any Drowsiness	0	0	0	0
Grade 3 Drowsiness	0	0	0	0
Related Drowsiness	0	0	0	0
Any Irritability	6	0	0	0
Grade 3 Irritability	0	0	0	0
Related Irritability	5	0	0	0
Any Loss of appetite	0	0	0	0
Grade 3 Loss of appetite	0	0	0	0
Related Loss of appetite	0	0	0	0

Any Fever	38	31	14	13
Grade 3 Fever	0	0	0	0
Related Fever	35	28	13	13

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any and Grade 3 solicited local symptoms. ^[13]
-----------------	---

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 30 millimeters (mm) of injection site.

End point type	Secondary
----------------	-----------

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following each dose.

Notes:

[13] - 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: Results were computed separately for sets of groups in this study.

End point values	7-11S Group	7-11NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Any Pain, Dose 1	7	10		
Grade 3 Pain, Dose 1	0	0		
Any Redness, Dose 1	0	0		
Grade 3 Redness, Dose 1	0	0		
Any Swelling, Dose 1	0	0		
Grade 3 Swelling, Dose 1	0	0		
Any Pain, Dose 2	5	7		
Grade 3 Pain, Dose 2	0	0		
Any Redness, Dose 2	0	0		
Grade 3 Redness, Dose 2	0	0		
Any Swelling, Dose 2	0	1		
Grade 3 Swelling, Dose 2	0	0		
Any Pain, Across Doses	12	15		
Grade 3 Pain, Across Doses	0	0		
Any Redness, Across Doses	0	0		
Grade 3 Redness, Across Doses	0	0		
Any Swelling, Across Doses	0	1		
Grade 3 Swelling, Across Doses	0	0		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with any, Grade 3 and related solicited general symptoms. ^[14]
-----------------	--

End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and fever [defined as rectal temperature equal to or above 38 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 fever = fever > 40.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary
----------------	-----------

End point timeframe:

During the 4-day (Days 0-3) post-vaccination period following each dose.

Notes:

[14] - 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: Results were computed separately for sets of groups in this study.

End point values	12-23S Group	12-23NS Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Any Drowsiness, Dose 1 [N=50,50]	0	0		
Grade 3 Drowsiness, Dose 1 [N=50,50]	0	0		
Related Drowsiness, Dose 1 [N=50,50]	0	0		
Any Irritability, Dose 1 [N=50,50]	1	0		
Grade 3 Irritability, Dose 1 [N=50,50]	0	0		
Related Irritability, Dose 1 [N=50,50]	1	0		
Any Loss of appetite, Dose 1 [N=50,50]	0	1		
Grade 3 Loss of appetite, Dose 1 [N=50,50]	0	0		
Related Loss of appetite, Dose 1 [N=50,50]	0	1		
Any Fever, Dose 1 [N=50,50]	21	15		
Grade 3 Fever, Dose 1 [N=50,50]	0	0		
Related Fever, Dose 1 [N=50,50]	21	13		
Any Drowsiness, Dose 2 [N=50,48]	0	0		
Grade 3 Drowsiness, Dose 2 [N=50,48]	0	0		
Related Drowsiness, Dose 2 [N=50,48]	0	0		
Any Irritability, Dose 2 [N=50,48]	1	0		
Grade 3 Irritability, Dose 2 [N=50,48]	0	0		
Related Irritability, Dose 2 [N=50,48]	1	0		
Any Loss of appetite, Dose 2 [N=50,48]	0	0		
Grade 3 Loss of appetite, Dose 2 [N=50,48]	0	0		
Related Loss of appetite, Dose 2 [N=50,48]	0	0		
Any Fever, Dose 2 [N=50,48]	12	12		
Grade 3 Fever, Dose 2 [N=50,48]	0	0		
Related Fever, Dose 2 [N=50,48]	10	9		

Any Drowsiness, Across Doses [N=50,50]	0	0		
Grade 3 Drowsiness, Across Doses [N=50,50]	0	0		
Related Drowsiness, Across Doses [N=50,50]	0	0		
Any Irritability, Across Doses [N=50,50]	2	0		
Grade 3 Irritability, Across Doses [N=50,50]	0	0		
Related Irritability, Across Doses [N=50,50]	2	0		
Any Loss of appetite, Across Doses [N=50,50]	0	1		
Grade 3 Loss of appetite, Across Doses [N=50,50]	0	0		
Related Loss of appetite, Across Doses [N=50,50]	0	1		
Any Fever, Across Doses [N=50,50]	29	20		
Grade 3 Fever, Across Doses [N=50,50]	0	0		
Related Fever, Across Doses [N=50,50]	28	17		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms: within 4 days after each vaccination dose.

Unsolicited symptoms: within 31 days after each vaccination.

SAEs: during the whole study 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	14.0
--------------------	------

Reporting groups

Reporting group title	<6S Group
-----------------------	-----------

Reporting group description:

Children below 6 months of age with sickle cell disease, receiving a 3-dose primary vaccination with 10Pn-PD-DiT vaccine at approximately 8-12-16 weeks of age and booster vaccination at 9-10 months of age. Subjects received DTPw-HBV/Hib + OPV as co-administered vaccines. The allowable intervals between the primary vaccination doses were 28-42 days.

Reporting group title	<6NS Group
-----------------------	------------

Reporting group description:

Healthy children below 6 months of age, receiving a 3-dose primary vaccination with 10Pn-PD-DiT vaccine at approximately 8-12-16 weeks of age and booster vaccination at 9-10 months of age. Subjects received DTPw-HBV/Hib + OPV as co-administered vaccines. The allowable intervals between the primary vaccination doses were 28-42 days.

Reporting group title	7-11S Group
-----------------------	-------------

Reporting group description:

Children between 7-11 months of age with sickle cell disease, receiving a 2-dose primary vaccination with 10Pn-PD-DiT vaccine starting at 7-11 months of age with an interval of at least 4 weeks (28-42 days) between primary doses. Subjects received a booster after an interval of 2 to 4 months since the previous dose.

Reporting group title	7-11NS Group
-----------------------	--------------

Reporting group description:

Healthy children between 7-11 months of age, receiving a 2-dose primary vaccination with 10Pn-PD-DiT vaccine starting at 7-11 months of age with an interval of at least 4 weeks (28-42 days) between primary doses. Subjects received a booster after an interval of 2 to 4 months since the previous dose.

Reporting group title	12-23S Group
-----------------------	--------------

Reporting group description:

Children between 12-23 months of age with sickle cell disease, receiving a 2-dose vaccination with 10Pn-PD-DiT vaccine starting at 12-23 months of age with an interval of 2 to 4 months between doses.

Reporting group title	12-23NS Group
-----------------------	---------------

Reporting group description:

Healthy children between 12-23 months of age, receiving a 2-dose vaccination with 10Pn-PD-DiT vaccine starting at 12-23 months of age with an interval of 2 to 4 months between doses.

Serious adverse events	<6S Group	<6NS Group	7-11S Group
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 50 (6.00%)	9 / 50 (18.00%)	3 / 50 (6.00%)
number of deaths (all causes)	1	1	1

number of deaths resulting from adverse events			
General disorders and administration site conditions			
Malnutrition			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pyrexia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Musculoskeletal and connective tissue disorders			
Osteomyelitis acute			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (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
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 50 (2.00%)	6 / 50 (12.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 1	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	3 / 50 (6.00%)	3 / 50 (6.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (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
Bronchitis			

subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (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
Enteritis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (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 rotavirus			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (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 Salmonella			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (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

Serious adverse events	7-11NS Group	12-23S Group	12-23NS Group
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 50 (8.00%)	2 / 50 (4.00%)	2 / 50 (4.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
General disorders and administration site conditions			
Malnutrition			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (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
Pyrexia			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (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

Musculoskeletal and connective tissue disorders			
Osteomyelitis acute			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (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
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	2 / 50 (4.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaria			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	2 / 50 (4.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (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
Bronchitis			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (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 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (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
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (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

Meningitis Salmonella			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (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
Urinary tract infection			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (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

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

Non-serious adverse events	<6S Group	<6NS Group	7-11S Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	48 / 50 (96.00%)	43 / 50 (86.00%)	31 / 50 (62.00%)
General disorders and administration site conditions			
Pain (Primary vaccination, Across Doses)			
alternative assessment type: Systematic			
subjects affected / exposed	17 / 50 (34.00%)	23 / 50 (46.00%)	12 / 50 (24.00%)
occurrences (all)	17	23	12
Pain (Booster vaccination, Across Doses)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	11 / 49 (22.45%)	6 / 49 (12.24%)	3 / 50 (6.00%)
occurrences (all)	11	6	3
Swelling (Primary vaccination, Across Doses)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Swelling (Booster vaccination, Across Doses)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	1 / 49 (2.04%)	0 / 49 (0.00%)	1 / 50 (2.00%)
occurrences (all)	1	0	1
Drowsiness (Primary vaccination, Across Doses)			

alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Irritability (Primary vaccination, Across Doses)			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 50 (6.00%)	6 / 50 (12.00%)	0 / 50 (0.00%)
occurrences (all)	3	6	0
Irritability (Booster vaccination, Across Doses)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
alternative assessment type: Systematic			
subjects affected / exposed ^[3]	6 / 49 (12.24%)	0 / 49 (0.00%)	0 / 50 (0.00%)
occurrences (all)	6	0	0
Loss of Appetite (Primary vaccination, Across Doses)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Fever (Primary vaccination, Across Doses)	Additional description: Fever was assessed rectally.		
alternative assessment type: Systematic			
subjects affected / exposed	48 / 50 (96.00%)	43 / 50 (86.00%)	31 / 50 (62.00%)
occurrences (all)	48	43	31
Fever (Booster vaccination, Across Doses)	Additional description: Fever was assessed rectally. Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
alternative assessment type: Systematic			
subjects affected / exposed ^[4]	38 / 49 (77.55%)	31 / 49 (63.27%)	14 / 50 (28.00%)
occurrences (all)	38	31	14
Pyrexia (Primary)			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	3 / 50 (6.00%)
occurrences (all)	0	0	3
Blood and lymphatic system disorders			
Sickle cell anaemia with crisis (Primary)			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	3 / 50 (6.00%)
occurrences (all)	0	0	3
Gastrointestinal disorders			

Diarrhoea (Primary) subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	3 / 50 (6.00%) 3
Diarrhoea (Booster) subjects affected / exposed ^[5] occurrences (all)	1 / 50 (2.00%) 1	2 / 50 (4.00%) 2	3 / 50 (6.00%) 3
Respiratory, thoracic and mediastinal disorders Cough (Primary) subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	5 / 50 (10.00%) 5	0 / 50 (0.00%) 0
Infections and infestations Malaria (Primary) subjects affected / exposed occurrences (all)	10 / 50 (20.00%) 10	7 / 50 (14.00%) 7	9 / 50 (18.00%) 9
Malaria (Booster) subjects affected / exposed ^[6] occurrences (all)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
	0 / 49 (0.00%) 0	8 / 49 (16.33%) 8	8 / 50 (16.00%) 8
Bronchitis (Primary) subjects affected / exposed occurrences (all)	9 / 50 (18.00%) 9	10 / 50 (20.00%) 10	3 / 50 (6.00%) 3
Gastroenteritis (Primary) subjects affected / exposed occurrences (all)	6 / 50 (12.00%) 6	5 / 50 (10.00%) 5	3 / 50 (6.00%) 3
Rhinitis (Primary) subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	7 / 50 (14.00%) 7	4 / 50 (8.00%) 4
Nasopharyngitis (Primary) subjects affected / exposed occurrences (all)	6 / 50 (12.00%) 6	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0
Gastrointestinal fungal infection (Primary) subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	5 / 50 (10.00%) 5	3 / 50 (6.00%) 3
Enteritis (Primary) subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	6 / 50 (12.00%) 6

Enteritis (Booster)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
subjects affected / exposed ^[7]	0 / 49 (0.00%)	2 / 49 (4.08%)	0 / 50 (0.00%)
occurrences (all)	0	2	0

Non-serious adverse events	7-11NS Group	12-23S Group	12-23NS Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 50 (58.00%)	29 / 50 (58.00%)	20 / 50 (40.00%)
General disorders and administration site conditions			
Pain (Primary vaccination, Across Doses)			
alternative assessment type: Systematic			
subjects affected / exposed	15 / 50 (30.00%)	13 / 50 (26.00%)	9 / 50 (18.00%)
occurrences (all)	15	13	9
Pain (Booster vaccination, Across Doses)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
alternative assessment type: Systematic			
subjects affected / exposed ^[1]	0 / 50 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Swelling (Primary vaccination, Across Doses)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences (all)	1	1	1
Swelling (Booster vaccination, Across Doses)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
alternative assessment type: Systematic			
subjects affected / exposed ^[2]	0 / 50 (0.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Drowsiness (Primary vaccination, Across Doses)			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 50 (2.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Irritability (Primary vaccination, Across Doses)			
alternative assessment type: Systematic			

subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	2 / 50 (4.00%) 2	0 / 50 (0.00%) 0
Irritability (Booster vaccination, Across Doses)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
alternative assessment type: Systematic subjects affected / exposed ^[3] occurrences (all)	0 / 50 (0.00%) 0	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Loss of Appetite (Primary vaccination, Across Doses) alternative assessment type: Systematic subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Fever (Primary vaccination, Across Doses)	Additional description: Fever was assessed rectally.		
alternative assessment type: Systematic subjects affected / exposed occurrences (all)	29 / 50 (58.00%) 39	29 / 50 (58.00%) 29	20 / 50 (40.00%) 20
Fever (Booster vaccination, Across Doses)	Additional description: Fever was assessed rectally. Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
alternative assessment type: Systematic subjects affected / exposed ^[4] occurrences (all)	13 / 50 (26.00%) 13	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Pyrexia (Primary) subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	0 / 50 (0.00%) 0	1 / 50 (2.00%) 1
Blood and lymphatic system disorders Sickle cell anaemia with crisis (Primary) subjects affected / exposed occurrences (all)	0 / 50 (0.00%) 0	10 / 50 (20.00%) 10	0 / 50 (0.00%) 0
Gastrointestinal disorders Diarrhoea (Primary) subjects affected / exposed occurrences (all)	1 / 50 (2.00%) 1	1 / 50 (2.00%) 1	7 / 50 (14.00%) 7
Diarrhoea (Booster) subjects affected / exposed ^[5] occurrences (all)	1 / 50 (2.00%) 1	0 / 1 (0.00%) 0	0 / 1 (0.00%) 0
Respiratory, thoracic and mediastinal			

disorders			
Cough (Primary)			
subjects affected / exposed	0 / 50 (0.00%)	1 / 50 (2.00%)	0 / 50 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Malaria (Primary)			
subjects affected / exposed	13 / 50 (26.00%)	10 / 50 (20.00%)	10 / 50 (20.00%)
occurrences (all)	13	10	10
Malaria (Booster)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
subjects affected / exposed ^[6]	4 / 50 (8.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	4	0	0
Bronchitis (Primary)			
subjects affected / exposed	8 / 50 (16.00%)	1 / 50 (2.00%)	4 / 50 (8.00%)
occurrences (all)	8	1	4
Gastroenteritis (Primary)			
subjects affected / exposed	9 / 50 (18.00%)	1 / 50 (2.00%)	6 / 50 (12.00%)
occurrences (all)	9	1	6
Rhinitis (Primary)			
subjects affected / exposed	3 / 50 (6.00%)	3 / 50 (6.00%)	4 / 50 (8.00%)
occurrences (all)	3	3	4
Nasopharyngitis (Primary)			
subjects affected / exposed	7 / 50 (14.00%)	3 / 50 (6.00%)	6 / 50 (12.00%)
occurrences (all)	7	3	6
Gastrointestinal fungal infection (Primary)			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Enteritis (Primary)			
subjects affected / exposed	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Enteritis (Booster)	Additional description: Groups 12-23S and 12-23NS were not included in the analysis since they received no booster dose, so the numbers presented for them are placeholder values.		
subjects affected / exposed ^[7]	3 / 50 (6.00%)	0 / 1 (0.00%)	0 / 1 (0.00%)
occurrences (all)	3	0	0

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: Solicited local and general symptoms have been tabulated only for subjects with a symptom sheet completed and who received all vaccine doses.

[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: Solicited local and general symptoms have been tabulated only for subjects with a symptom sheet completed and who received all vaccine doses.

[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: Solicited local and general symptoms have been tabulated only for subjects with a symptom sheet completed and who received all vaccine doses.

[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: Solicited local and general symptoms have been tabulated only for subjects with a symptom sheet completed and who received all vaccine doses.

[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: Less subjects received the booster dose than the primary vaccination.

[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: Less subjects received the booster dose than the primary vaccination.

[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: Less subjects received the booster dose than the primary vaccination.

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