Clinical trial results:
A Phase II, open-label, randomised controlled study to evaluate the safety, reactogenicity and immunogenicity of GSK Biologicals' candidate tuberculosis (TB) vaccine (M72/AS01E) when administered intramuscularly according to different immunisation schedules to healthy infants, living in a TB-endemic region.

Summary

EudraCT number	2012-004380-44
Trial protocol	Outside EU/EEA
Global end of trial date	16 March 2012

Results information

Result version number	v1
This version publication date	11 May 2016
First version publication date	18 July 2015

Trial information

Trial identification

Sponsor protocol code	112899

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01098474
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)	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	17 July 2012
Is this the analysis of the primary completion data?	Yes
Primary completion date	30 April 2011
Global end of trial reached?	Yes
Global end of trial date	16 March 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety of 1 or 2 doses of the TB candidate vaccine when given to healthy infants concomitantly with the EPI regimen containing the DTPw-HBV/Hib, 7Pn and OPV vaccines.
· To evaluate the safety of 1 or 2 doses of the TB candidate vaccine when given to healthy infants after receiving the EPI vaccines containing the DTPw-HBV/Hib, 7Pn and OPV vaccines.

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	07 July 2010
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Gambia: 301
Worldwide total number of subjects	301
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)	301

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.

Pre-assignment period milestones

Number of subjects started	301
Number of subjects completed	300

Pre-assignment subject non-completion reasons

Reason: Number of subjects	No vaccination received: 1

Period 1

Period 1 title	Active Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	SB692342 2 dose Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	GSK Biologicals' candidate tuberculosis vaccine (692342)
Investigational medicinal product code	
Other name	SB692342
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses of 0,5 mL vaccine were administered intramuscularly in the anterolateral region of the right tight, on a 0, 1 month schedule after having completed their primary EPI regimen.

Arm title	SB692342 1 dose Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	GSK Biologicals' candidate tuberculosis vaccine (692342)
Investigational medicinal product code	
Other name	SB692342
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of 0,5 mL vaccine was administered intramuscularly in the anterolateral region of the right tight, at Month 0,after having completed their primary EPI regimen.

Arm title	Control Menjugate Group

Arm description: -

Arm type	Active comparator

Investigational medicinal product name	Menjugate™
Investigational medicinal product code	
Other name	MenC
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of the 0,5 mL control vaccine were administered intramuscularly in the anterolateral region of the right tight, on a 0, 1, 7 months schedule. The first 2 doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

Arm title	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group

Arm description: -

Arm type	Experimental
Investigational medicinal product name	GSK Biologicals' candidate tuberculosis vaccine (692342)
Investigational medicinal product code	
Other name	SB692342
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses of GSK's investigational vaccine 692342 (0,5 mL)were administered, 1 Month apart, intramuscularly in the anterolateral region of the right tight, concomintantly with the last two doses of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ administered orally and Prevnar® administered intramuscularly in the right arm.

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

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix™ HB+Hib, received intramuscularly in the anterolateral region of the left tight, Polio Sabin™ and Prevnar® were administered together with two doses of GSK's investigational vaccine 692342.

Investigational medicinal product name	Polio Sabin™
Investigational medicinal product code	
Other name	OPV
Pharmaceutical forms	Suspension for injection
Routes of administration	Oral use

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ received orally and Prevnar® were administered together with two doses of GSK's investigational vaccine 692342.

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

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® received instramuscularly in the right arm, were administered together with two doses of GSK's investigational vaccine 692342.

Arm title	SB692392 1 dose +Tritanrix + Prevnar+ Polio Sabin Group

Arm description: -

Arm type	Experimental

Investigational medicinal product name	GSK Biologicals' candidate tuberculosis vaccine (692342)
Investigational medicinal product code	
Other name	SB692342
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of GSK's investigational vaccine 692342 (0,5 mL)were administered, 1 Month apart, intramuscularly in the anterolateral region of the right tight, concommitantly with the last dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ administered orally and Prevnar® administered intramuscularly in the right arm..

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

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix™ HB+Hib, received intramuscularly in the anterolateral region of the left tight, Polio Sabin™ and Prevnar® were administered together with one dose of GSK's investigational vaccine 692342.

Investigational medicinal product name	Polio Sabin™
Investigational medicinal product code	
Other name	OPV
Pharmaceutical forms	Suspension for injection
Routes of administration	Oral use

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ received orally and Prevnar® were administered together with one dose of GSK's investigational vaccine 692342..

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

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® received intramuscularly in the right arm, were administered together with one dose of GSK's investigational vaccine 692342.

Arm title	Control Tritanrix + Prevnar + Polio Sabin Group

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Tritanrix™ HB+Hib
Investigational medicinal product code	
Other name	DTPw-HBV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® were administered on a 0, 1, 2 Months schedule.

Investigational medicinal product name	Polio Sabin™
Investigational medicinal product code	
Other name	OPV
Pharmaceutical forms	Suspension for injection
Routes of administration	Oral use

Dosage and administration details:

Three dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® were

administered on a 0, 1, 2 Months schedule.

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

Dosage and administration details:

Three dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® were administered on a 0, 1, 2 Months schedule.

Number of subjects in period 1[1]	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group
Started	50	50	50
Completed	48	49	45
Not completed	2	1	5
Consent withdrawn by subject	1	1	2
Unspecified	-	-	3
Lost to follow-up	1	-	-

Number of subjects in period 1[1]	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose +Tritanrix + Prevnar+ Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group
Started	49	52	49
Completed	49	52	49
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 301 subjects enrolled in the study, but 1 was eliminated as he/she received no vaccination, hence 300 subjects started the study.

Period 2

Period 2 title	Follow-up Phase
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes

Arm title	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	GSK Biologicals' candidate tuberculosis vaccine (692342)
Investigational medicinal product code	
Other name	SB692342
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses of GSK's investigational vaccine 692342 (0,5 mL)were administered, 1 Month apart, intramuscularly in the anterolateral region of the right tight, concomintantly with the last two doses of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ administered orally and Prevnar® administered intramuscularly in the right arm.

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

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix™ HB+Hib, received intramuscularly in the anterolateral region of the left tight, Polio Sabin™ and Prevnar® were administered together with two doses of GSK's investigational vaccine 692342.

Investigational medicinal product name	Polio Sabin™
Investigational medicinal product code	
Other name	OPV
Pharmaceutical forms	Suspension for injection
Routes of administration	Oral use

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ received orally and Prevnar® were administered together with two doses of GSK's investigational vaccine 692342.

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

Dosage and administration details:

The last two doses of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® received instramuscularly in the right arm, were administered together with two doses of GSK's investigational vaccine 692342.

Arm title	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	GSK Biologicals' candidate tuberculosis vaccine (692342)
Investigational medicinal product code	
Other name	SB692342
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of GSK's investigational vaccine 692342 (0,5 mL)were administered, 1 Month apart, intramuscularly in the anterolateral region of the right tight, concomintantly with the last dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ administered orally and Prevnar® administered intramuscularly in the right arm.

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

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix™ HB+Hib, received intramuscularly in the anterolateral region of the left tight, Polio Sabin™ and Prevnar® were administered together with one dose of GSK's investigational vaccine 692342.

Investigational medicinal product name	Polio Sabin™
Investigational medicinal product code	
Other name	OPV
Pharmaceutical forms	Suspension for injection
Routes of administration	Oral use

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ received orally and Prevnar® were administered together with one dose of GSK's investigational vaccine 692342.

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

Dosage and administration details:

The last dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® received instramuscularly in the right arm, were administered together with one dose of GSK's investigational vaccine 692342.

Arm title	Control Tritanrix + Prevnar + Polio Sabin Group

Arm description: -

Arm type	Active comparator
Investigational medicinal product name	Tritanrix™ HB+Hib
Investigational medicinal product code	
Other name	DTPw-HBV/Hib
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® were administered on a 0, 1, 2 Months schedule.

Investigational medicinal product name	Polio Sabin™
Investigational medicinal product code	
Other name	OPV
Pharmaceutical forms	Suspension for injection
Routes of administration	Oral use

Dosage and administration details:

Three dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® were administered on a 0, 1, 2 Months schedule.

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

Dosage and administration details:

Three dose of the primary EPI regimen containing Tritanrix™ HB+Hib, Polio Sabin™ and Prevnar® were administered on a 0, 1, 2 Months schedule.

Arm title	SB692342 2 dose Group

Arm description: -	
Arm type	Experimental
Investigational medicinal product name	GSK Biologicals' candidate tuberculosis vaccine (692342)
Investigational medicinal product code	
Other name	SB692342
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Two doses of 0,5 mL vaccine were administered intramuscularly in the anterolateral region of the right tight, on a 0, 1 month schedule after having completed their primary EPI regimen.

Arm title	SB692342 1 dose Group
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	GSK Biologicals' candidate tuberculosis vaccine (692342)
Investigational medicinal product code	
Other name	SB692342
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

One dose of 0,5 mL vaccine was administered intramuscularly in the anterolateral region of the right tight, at Month 0,after having completed their primary EPI regimen.

Arm title	Control Menjugate Group
Arm description: -	
Arm type	Active comparator
Investigational medicinal product name	Menjugate™
Investigational medicinal product code	
Other name	MenC
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

Three doses of the 0,5 mL control vaccine were administered intramuscularly in the anterolateral region of the right tight, on a 0, 1, 7 months schedule. The first 2 doses were administered 1 month apart during the primary vaccination phase and the third dose was administered 6 months after the last primary vaccination dose.

Number of subjects in period 2	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group
Started	49	52	49
Completed	47	50	44
Not completed	2	2	5
Consent withdrawn by subject	2	-	1
' Travelled out of study area '	-	1	-
Unspecified	-	-	4
Lost to follow-up	-	1	-

Number of subjects in period 2	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group
Started	48	49	45

Completed	48	49	45
Not completed	0	0	0
Consent withdrawn by subject	-	-	-
' Travelled out of study area '	-	-	-
Unspecified	-	-	-
Lost to follow-up	-	-	-

Baseline characteristics

Reporting groups	
Reporting group title	SB692342 2 dose Group
Reporting group description: -	
Reporting group title	SB692342 1 dose Group
Reporting group description: -	
Reporting group title	Control Menjugate Group
Reporting group description: -	
Reporting group title	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	
Reporting group title	SB692392 1 dose +Tritanrix + Prevnar+ Polio Sabin Group
Reporting group description: -	
Reporting group title	Control Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	

Reporting group values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate 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: months			
arithmetic mean	5.8	5.7	5.7
standard deviation	± 0.68	± 0.61	± 0.65
Gender categorical Units: Subjects			
Female	34	20	23
Male	16	30	27

Reporting group values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose +Tritanrix + Prevnar+ Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group
Number of subjects	49	52	49
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days)			

Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous			
Units: months			
arithmetic mean	2.1	2	2.1
standard deviation	± 0.28	± 0.19	± 0.31
Gender categorical			
Units: Subjects			
Female	25	16	23
Male	24	36	26

Reporting group values	Total		
Number of subjects	300		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: months			
arithmetic mean			
standard deviation	-		
Gender categorical			
Units: Subjects			
Female	141		
Male	159		

End points

End points reporting groups

Reporting group title	SB692342 2 dose Group
Reporting group description: -	
Reporting group title	SB692342 1 dose Group
Reporting group description: -	
Reporting group title	Control Menjugate Group
Reporting group description: -	
Reporting group title	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	
Reporting group title	SB692392 1 dose +Tritanrix + Prevnar+ Polio Sabin Group
Reporting group description: -	
Reporting group title	Control Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	
Reporting group title	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	
Reporting group title	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	
Reporting group title	Control Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	
Reporting group title	SB692342 2 dose Group
Reporting group description: -	
Reporting group title	SB692342 1 dose Group
Reporting group description: -	
Reporting group title	Control Menjugate Group
Reporting group description: -	

Primary: Number of subjects with grade 3 solicited local symptoms

End point title	Number of subjects with grade 3 solicited local symptoms[1][2]
End point description:	

End point type	Primary

End point timeframe:

During the 7 day (Days 0-6) post vaccination, after each dose and across doses

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	50	50	
Units: Subjects				
Grade 3 Pain, D1 (N=50,50,50)	0	0	0	
Grade 3 Swelling, D1 (N=50,50,50)	0	0	0	
Grade 3 Pain, D2 (N=49,0 ,48)	0	0	0	
Grade 3 Swelling, D2 (N=49,0,48)	0	0	0	
Grade 3 Pain, Across (N=50,50,50)	0	0	0	
Grade 3 Swelling, Across (N=50,50,50)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 solicited local symptoms

End point title	Number of subjects with grade 3 solicited local symptoms[3]

End point description:

Solicited local symptoms were only collected after Dose 2 of EPI vaccination.

End point type	Primary

End point timeframe:

During the 7 day (Days 0-6) post vaccination, after each dose and across doses

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	52	48	
Units: Subjects				
Grade 3 Pain, D2 (N=47,0 ,47)	0	0	0	
Grade 3 Swelling, D2 (N=47,0,47)	2	0	2	
Grade 3 Pain, D3 (N=47,52,48)	2	0	0	
Grade 3 Swelling, D3 (N=47,52,48)	3	6	3	
Grade 3 Pain, Across (N=47,52,48)	2	0	0	
Grade 3 Swelling, Across (N=47,52,48)	3	6	5	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 solicited general symptoms

End point title	Number of subjects with grade 3 solicited general

End point description:

End point type	Primary

End point timeframe:

During the 7 day (Days 0-6) post vaccination, after each dose and across doses

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	50	50	
Units: Subjects				
Grade 3 Drowsiness, D1 (N=50,50,50)	0	0	0	
Grade 3 Irritability, D1 (N=50,50,50)	0	0	0	
Grade 3 Loss of appetite, D1 (N=50,50,50)	0	0	0	
Grade 3 Temperature /Axillary, D1 (N=50,50,50)	0	0	0	
Grade 3 Drowsiness, D2 (N=49,0 ,48)	0	0	0	
Grade 3 Irritability, D2 (N=49,0,48)	0	0	0	
Grade 3 Loss of appetite, D2 (N=49,0,48)	0	0	0	
Grade 3 Temperature/Axillary, D2 (N=49,0,48)	0	0	1	
Grade 3 Drowsiness, Across (N=50,50,50)	0	0	0	
Grade 3 Irritability, Across (N=50,50,50)	0	0	0	
Grade 3 Loss of appetite, Across (N=50,50,50)	0	0	0	
Grade 3 Fever/Axillary, Across (N=50,50,50)	0	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 solicited general symptoms

End point title	Number of subjects with grade 3 solicited general symptoms[6]

End point description:

Solicited local symptoms were only collected after Dose 2 of EPI vaccination.

End point type	Primary

End point timeframe:

During the 7 day (Days 0-6) post vaccination, after each dose and across doses

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	52	48	
Units: Subjects				
Grade 3 Drowsiness, D2 (N=47,0 ,47)	0	0	0	
Grade 3 Irritability, D2 (N=47,0,47)	0	0	0	
Grade 3 Loss of appetite, D2 (N=47,0,47)	0	0	0	
Grade 3 Temperature/Axillary, D2 (N=47,0,47)	0	0	0	
Grade 3 Drowsiness, D3 (N=47,52,48)	0	0	0	
Grade 3 Irritability, D3 (N=47,52,48)	2	0	0	
Grade 3 Loss of appetite, D3 (N=47,52,48)	0	0	0	
Grade 3 Temperature/Axillary, D3 (N=47,52,48)	0	0	0	
Grade 3 Drowsiness, Across (N=47,52,48)	0	0	0	
Grade 3 Irritability, Across (N=47,52,48)	2	0	0	
Grade 3 Loss of appetite, Across (N=47,52,48)	0	0	0	
Grade 3 Fever/Axillary, Across (N=47,52,48)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 unsolicited adverse events (AEs)

End point title	Number of subjects with grade 3 unsolicited adverse events (AEs)[7][8]

End point description:

End point type	Primary

End point timeframe:

During the 30 day (Days 0-29) post vaccination after each dose

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	47
Units: Subjects				
Grade 3 AEs	28	27	26	25

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	48		
Units: Subjects				
Grade 3 AEs	14	22		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with serious adverse events (SAEs)[9][10]

End point description:

End point type	Primary

End point timeframe:

From study start (Day 0) up to Month 1 of the primary vaccination

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	49
Units: Subjects				
Any SAEs	0	0	1	0

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	49		
Units: Subjects				
Any SAEs	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[11][12]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Before vaccination (PRE)

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	49
Units: Subjects				
Haem, PRE, Grade 3	0	0	0	0

WBC, PRE, Grade 3	0	0	0	0
PLA, PRE, Grade 3	0	0	0	0
ALA, PRE, Grade 3	0	0	0	0
CREA PRE, Grade 3	0	0	0	0

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	49		
Units: Subjects				
Haem, PRE, Grade 3	0	0		
WBC, PRE, Grade 3	0	0		
PLA, PRE, Grade 3	0	0		
ALA, PRE, Grade 3	0	0		
CREA PRE, Grade 3	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[13][14]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Seven days post Dose 1 [PI(D7)]

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	50	50	
Units: Subjects				
Haem, PI(D7), Grade 3	0	0	0	
WBC, PI(D7) Grade 3	0	0	0	

PLA, PI(D7), Grade 3	0	0	0	
ALA, PI(D7), Grade 3	0	0	0	
CREA PI(D7), Grade 3	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[15][16]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Seven days post Dose 2 [PII(D37)]

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[16] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	49	52
Units: Subjects				
Haem, PII(D37), Grade 3	0	0	0	0
WBC, PII(D37) Grade 3	0	0	0	0
PLA, PII(D37), Grade 3	0	0	0	0
ALA, PII(D37), Grade 3	0	0	0	0
CREA PII(D37), Grade 3	0	0	0	0

End point values	Control Tritanrix + Prevnar + Polio Sabin Group			
Subject group type	Reporting group			
Number of subjects analysed	49			
Units: Subjects				
Haem, PII(D37), Grade 3	0			
WBC, PII(D37) Grade 3	0			

PLA, PII(D37), Grade 3	0			
ALA, PII(D37), Grade 3	0			
CREA PII(D37), Grade 3	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[17]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Seven days post Dose 3 [PIII(D67)]

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	52	49	
Units: Subjects				
Haem, PIII(D67), Grade 3	0	0	0	
WBC, PIII(D67) Grade 3	0	0	0	
PLA, PIII(D67), Grade 3	0	0	0	
ALA, PIII(D67), Grade 3	0	0	0	
CREA PIII(D67), Grade 3	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[18][19]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

One Month post Dose 1 [PI(M1)]

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[19] - 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 for haematological and biochemical parameters were reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	50	50	50	
Units: Subjects				
Haem, PI(M1), Grade 3	0	0	0	
WBC, PI(M1) Grade 3	0	0	0	
PLA, PI(M1), Grade 3	0	0	0	
ALA, PI(M1), Grade 3	0	0	0	
CREA PI(M1), Grade 3	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[20][21]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

One Month post Dose 2 [PII(M2)]

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[21] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	Control Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Haem, PII(M2), Grade 3	0	0		
WBC, PII(M2) Grade 3	0	0		

PLA, PII(M2), Grade 3	0	0		
ALA, PII(M2), Grade 3	0	0		
CREA PII(M2), Grade 3	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[22]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

One Month post Dose 3 [PIII(M3)]

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	52	49	
Units: Subjects				
Haem, PIII(M3), Grade 3	0	0	0	
WBC, PIII(M3) Grade 3	0	0	0	
PLA, PIII(M3), Grade 3	0	0	0	
ALA, PIII(M3), Grade 3	0	0	0	
CREA PIII(M3), Grade 3	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[23][24]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Six Months post Dose 1 [PI(M6)]

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[24] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 1 dose Group			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: Subjects				
Haem, PI(M6), Grade 3	0			
WBC, PI(M6) Grade 3	0			
PLA, PI(M6), Grade 3	0			
ALA, PI(M6), Grade 3	0			
CREA PI(M6), Grade 3	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[25][26]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Six Months post Dose 2 [PII(M7)]

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[26] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	Control Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Haem, PII(M7), Grade 3	0	0		
WBC, PII(M7) Grade 3	0	0		
PLA, PII(M7), Grade 3	0	0		

ALA, PII(M7), Grade 3	0	0		
CREA PII(M7), Grade 3	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[27][28]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Six Months post Dose 3 [PIII(M13)]

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[28] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	Control Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Haem, PIII(M13), Grade 3	0	0		
WBC, PIII(M13) Grade 3	0	0		
PLA, PIII(M13), Grade 3	0	0		
ALA, PIII(M13), Grade 3	0	0		
CREA PIII(M13), Grade 3	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[29][30]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Twelve Months post Dose 1 [PI(M12)]

Notes:

[29] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[30] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group			
Subject group type	Reporting group			
Number of subjects analysed	50			
Units: Subjects				
Haem, PI(M12), Grade 3	0			
WBC, PI(M12) Grade 3	0			
PLA, PI(M12), Grade 3	0			
ALA, PI(M12), Grade 3	0			
CREA PI(M12), Grade 3	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[31][32]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Twelve Months post Dose 2 [PII(M13)]

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.
[32] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	Control Menjugate Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	50	50		
Units: Subjects				
Haem, PII(M13), Grade 3	0	0		
WBC, PII(M13) Grade 3	0	0		
PLA, PII(M13), Grade 3	0	0		
ALA, PII(M13), Grade 3	0	0		
CREA PII(M13), Grade 3	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[33]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Twelve Months post Dose 3

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	52	49	
Units: Subjects				
Haem, PIII(M14), Grade 3	0	0	0	
WBC, PIII(M14) Grade 3	0	0	0	
PLA, PIII(M14), Grade 3	0	0	1	
ALA, PIII(M14), Grade 3	0	0	0	
CREA PIII(M14), Grade 3	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with grade 3 haematological and biochemical levels

End point title	Number of subjects with grade 3 haematological and biochemical levels[34]

End point description:

Haematological/Biochemical parameters assessed were: Haemoglobin (Haem), White Blood Cells (WBC), Platelets (PLA), Alanine Aminotransferase (ALA) and Creatinine (CREA).

End point type	Primary

End point timeframe:

Six Months post Dose 3 [PIII(M8)]

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	50	49	
Units: Subjects				
Haem, PIII(M8), Grade 3	0	0	0	
WBC, PIII(M8) Grade 3	0	0	0	
PLA, PIII(M8), Grade 3	0	0	0	
ALA, PIII(M8), Grade 3	0	1	0	
CREA PIII(M8), Grade 3	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers[35]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2),Interferon-gamma (INF-γ),Tumour necrosis factor-alpha (TNF-α) and CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

Before vaccination (PRE)

Notes:

[35] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	42	34	36
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, PRE	47 (23 to 87)	42.5 (22 to 71)	44.5 (11 to 65)	59.5 (30.5 to 125)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), PRE	1 (1 to 1)	1 (1 to 12)	1 (1 to 15)	1 (1 to 24.5)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), PRE	1 (1 to 12)	1 (1 to 1)	1 (1 to 1)	1 (1 to 12)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), PRE	1 (1 to 11)	1 (1 to 1)	1 (1 to 1)	1 (1 to 13)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), PRE	14 (1 to 51)	11.5 (1 to 41)	1 (1 to 16)	1 (1 to 28)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), PRE	1 (1 to 12)	1 (1 to 12)	1 (1 to 1)	1 (1 to 24)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), PRE	1 (1 to 12)	1 (1 to 12)	1 (1 to 11)	1 (1 to 6)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 11.5)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), PRE	1 (1 to 38)	1 (1 to 40)	1 (1 to 40)	5.5 (1 to 29.5)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 12.5)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), PRE	1 (1 to 11)	1 (1 to 19)	1.5 (1 to 14)	1 (1 to 27.5)
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), PRE	1 (1 to 11)	1 (1 to 13)	1 (1 to 22)	1 (1 to 21.5)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	39		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, PRE	88 (27 to 181)	52 (33 to 149)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), PRE	14 (1 to 53)	1 (1 to 30)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), PRE	1 (1 to 17)	1 (1 to 14)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), PRE	1 (1 to 13)	1 (1 to 1)		

CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+IINF-γ (-), PRE	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), PRE	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), PRE	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), PRE	1 (1 to 15)	1 (1 to 13)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), PRE	3 (1 to 62)	1 (1 to 52)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), PRE	1 (1 to 27)	1 (1 to 27)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), PRE	1 (1 to 1)	1 (1 to 16)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), PRE	1 (1 to 20)	1 (1 to 15)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), PRE	28 (1 to 63)	20 (1 to 62)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), PRE	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), PRE	1 (1 to 11)	1 (1 to 21)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), PRE	12 (1 to 47)	15 (1 to 49)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers[36]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

Seven Days post each dose (D7)

Notes:

[36] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	43	37	42
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				

CD4 all doubles, D7	499 (250 to 1267)	128 (83 to 379)	55 (33 to 81)	593.5 (269 to 1094)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), D7	24 (1 to 83)	1 (1 to 39)	1 (1 to 15)	42.5 (14 to 66)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), D7	47 (15 to 143)	12 (1 to 25)	1 (1 to 12)	61.5 (18 to 157)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), D7	25 (1 to 103)	1 (1 to 26)	1 (1 to 1)	19.5 (1 to 71)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), D7	65 (12 to 286)	24 (1 to 52)	1 (1 to 1)	82.5 (29 to 320)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), D7	1 (1 to 15)	1 (1 to 1)	1 (1 to 1)	1 (1 to 22)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), D7	1 (1 to 32)	1 (1 to 11)	1 (1 to 1)	11 (1 to 38)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), D7	19 (9 to 61)	1 (1 to 19)	1 (1 to 1)	36.5 (1 to 105)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), D7	52 (1 to 144)	24 (1 to 102)	9 (1 to 63)	112 (25 to 297)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), D7	12 (1 to 32)	1 (1 to 24)	1 (1 to 12)	14.5 (1 to 45)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), D7	64 (12 to 107)	3 (1 to 24)	1 (1 to 13)	35.5 (1 to 88)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), D7	173 (38 to 232)	22 (1 to 86)	1 (1 to 1)	102 (31 to 237)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), D7	576 (245 to 1126)	138 (42 to 208)	1 (1 to 45)	493 (309 to 960)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), D7	1 (1 to 18)	1 (1 to 11)	1 (1 to 1)	1 (1 to 36)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), D7	25 (10 to 58)	1 (1 to 28)	11 (1 to 21)	27.5 (5 to 85)
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), D7	232 (85 to 444)	30 (5 to 69)	1 (1 to 17)	160.5 (61 to 314)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	44		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, D7	174 (67 to 321)	52.5 (33 to 85)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), D7	16 (1 to 43)	1 (1 to 19)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), D7	12 (1 to 29)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), D7	13 (1 to 38)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), D7	14 (1 to 44)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), D7	1 (1 to 12)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), D7	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), D7	13 (1 to 49)	1 (1 to 13)		

CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), D7	21 (1 to 58)	1 (1 to 37)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), D7	1 (1 to 21)	11.5 (1 to 15.5)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), D7	1 (1 to 13)	1 (1 to 7.5)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), D7	22 (1 to 67)	1 (1 to 14.5)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), D7	26 (1 to 134)	1 (1 to 42.5)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), D7	1 (1 to 13)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), D7	1 (1 to 20)	1 (1 to 13.5)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), D7	40 (12 to 91)	14 (1 to 44.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers[37]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

One Month post each dose (M1)

Notes:

[37] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	44	34	43
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, M1	640 (403 to 1200)	173.5 (93.5 to 476)	31 (22 to 66)	859 (348 to 1950)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M1	52 (1 to 157)	17 (1 to 63)	1 (1 to 12)	50 (12 to 253)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M1	142 (48 to 300)	30 (11.5 to 82.5)	1 (1 to 12)	195 (66 to 408)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M1	14 (1 to 45)	1 (1 to 14)	1 (1 to 1)	24 (1 to 132)

CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), M1	109 (49 to 143)	27 (1 to 59)	1 (1 to 1)	138 (56 to 327)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M1	1 (1 to 19)	1 (1 to 1)	1 (1 to 1)	17 (1 to 37)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M1	15 (1 to 44)	1 (1 to 6)	1 (1 to 1)	14 (1 to 63)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M1	14 (1 to 41)	1 (1 to 12)	1 (1 to 1)	24 (1 to 64)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M1	51 (1 to 107)	1 (1 to 50.5)	1 (1 to 42)	51 (1 to 162)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M1	28 (1 to 109)	1 (1 to 45)	1 (1 to 1)	20 (1 to 60)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), M1	95 (32 to 251)	28 (1 to 59.5)	127 (63 to 257)	127 (63 to 257)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M1	57 (26 to 204)	19 (1 to 76)	1 (1 to 1)	63 (27 to 118)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M1	431 (239 to 838)	115.5 (42.5 to 277.5)	3 (1 to 33)	449 (253 to 793)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M1	1 (1 to 27)	1 (1 to 7)	1 (1 to 1)	1 (1 to 29)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M1	53 (5 to 106)	9.5 (1 to 38)	1 (1 to 15)	51 (3 to 108)
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), M1	54 (18 to 107)	19.5 (1 to 49)	1 (1 to 14)	71 (25 to 141)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	42		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, M1	235 (142 to 485)	55.5 (30 to 115)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M1	25 (1 to 88)	12 (1 to 26)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M1	56 (14 to 88)	1 (1 to 17)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M1	12 (1 to 26)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), M1	28 (12 to 63)	1 (1 to 12)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M1	1 (1 to 12)	1 (1 to 11)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M1	1 (1 to 1)	1 (1 to 12)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M1	12 (1 to 24)	1 (1 to 14)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M1	16 (1 to 96)	1 (1 to 42)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M1	12 (1 to 24)	1 (1 to 15)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), M1	15 (1 to 78)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M1	24 (1 to 44)	1 (1 to 1)		

CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M1	127 (36 to 257)	23 (1 to 66)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M1	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M1	19 (1 to 58)	11 (1 to 35)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), M1	11 (1 to 48)	1 (1 to 21)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers[38]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

Six Months post each dose (M6)

Notes:

[38] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	36	42	34	40
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, M6	633 (324 to 1062)	107.5 (47 to 184)	39 (23 to 71)	512 (318.5 to 992.5)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M6	63 (18.5 to 129)	12 (1 to 28)	1 (1 to 13)	65 (13 to 125)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M6	223 (78 to 403)	28 (1 to 50)	1 (1 to 15)	202.5 (101.5 to 434)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M6	18.5 (1 to 25.5)	1 (1 to 1)	1 (1 to 1)	15.5 (1 to 29)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+IINF-γ (-), M6	68.5 (40.5 to 163)	1 (1 to 22)	1 (1 to 1)	65 (34.5 to 184.5)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 13)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M6	12 (1 to 20.5)	1 (1 to 11)	1 (1 to 1)	1 (1 to 26)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M6	1 (1 to 6.5)	1 (1 to 1)	1 (1 to 11)	1 (1 to 28)

CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M6	16.5 (1 to 71)	1 (1 to 28)	1 (1 to 39)	40.5 (1 to 95.5)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M6	13.5 (1 to 59.5)	1 (1 to 14)	1 (1 to 1)	13 (1 to 52.5)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), M6	72 (38 to 206.5)	12 (1 to 28)	1 (1 to 13)	86.5 (27 to 156.5)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M6	31 (1 to 84.5)	1 (1 to 13)	1 (1 to 1)	26 (7 to 55)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M6	310.5 (60 to 591.5)	35.5 (1 to 68)	10 (1 to 27)	171.5 (126.5 to 369)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M6	1 (1 to 18)	1 (1 to 1)	1 (1 to 1)	1 (1 to 13)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M6	19 (1 to 71.5)	1 (1 to 12)	1 (1 to 14)	27 (1 to 61)
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), M6	19.5 (1 to 58)	1 (1 to 14)	1 (1 to 18)	14 (1 to 46.5)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	44		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, M6	107 (72 to 191)	41 (23 to 73.5)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M6	16 (1 to 48)	1 (1 to 13.5)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M6	17 (1 to 64)	1 (1 to 12.5)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M6	1 (1 to 13)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+IINF-γ (-), M6	13 (1 to 41)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M6	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M6	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M6	1 (1 to 1)	1 (1 to 13)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M6	2 (1 to 44)	13.5 (1 to 48.5)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M6	1 (1 to 17)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), M6	5 (1 to 40)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M6	1 (1 to 16)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M6	48 (8 to 99)	12.5 (1 to 41)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M6	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M6	1 (1 to 14)	1 (1 to 13.5)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), M6	1 (1 to 16)	1 (1 to 14)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)4+ T cells per million cells expressing at least two different immune markers[39]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

Twelve Months post each dose (M12)

Notes:

[39] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	45	33	41
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, M12	456.5 (237 to 1062)	104 (59 to 201)	38 (22 to 61)	403 (245 to 745)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M12	51 (18 to 145)	16 (1 to 42)	1 (1 to 1)	65 (18 to 99)
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M12	176 (73 to 424)	28 (12 to 52)	1 (1 to 14)	144 (80 to 329)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M12	7 (1 to 39)	1 (1 to 1)	1 (1 to 1)	13 (1 to 40)
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), M12	56.5 (24 to 145)	13 (1 to 21)	1 (1 to 1)	67 (24 to 149)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M12	1 (1 to 13)	1 (1 to 1)	1 (1 to 1)	1 (1 to 13)
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M12	12.5 (1 to 37)	1 (1 to 1)	1 (1 to 1)	1 (1 to 23)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M12	1 (1 to 12)	1 (1 to 13)	1 (1 to 12)	1 (1 to 17)
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M12	10.5 (1 to 57)	1 (1 to 48)	22 (1 to 58)	29 (1 to 81)
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M12	13 (1 to 29)	1 (1 to 16)	1 (1 to 1)	1 (1 to 17)

CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), M12	60 (15 to 138)	12 (1 to 21)	1 (1 to 1)	39 (13 to 91)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M12	21 (1 to 56)	1 (1 to 12)	1 (1 to 1)	19 (1 to 40)
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M12	179 (84 to 283)	30 (1 to 66)	1 (1 to 20)	155 (74 to 300)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M12	1 (1 to 15)	1 (1 to 1)	1 (1 to 1)	1 (1 to 12)
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M12	3.5 (1 to 38)	3 (1 to 40)	1 (1 to 27)	1 (1 to 35)
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), M12	14.5 (1 to 49)	1 (1 to 25)	1 (1 to 27)	2 (1 to 54)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	43		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD4 all doubles, M12	98 (52 to 157)	41 (22 to 79)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M12	14 (1 to 48)	1 (1 to 14)		
CD4.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-), M12	26 (12 to 47)	1 (1 to 12)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+), M12	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-), M12	1 (1 to 16)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+), M12	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-), M12	1 (1 to 13)	1 (1 to 12)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+), M12	1 (1 to 1)	1 (1 to 13)		
CD4.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-), M12	14 (1 to 67)	13 (1 to 72)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+), M12	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-), M12	1 (1 to 12)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+), M12	1 (1 to 12)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-), M12	50 (22 to 87)	3 (1 to 25)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+), M12	1 (1 to 1)	1 (1 to 1)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-), M12	1 (1 to 39)	1 (1 to 19)		
CD4.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+), M12	1 (1 to 25)	1 (1 to 41)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers[40]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

Before vaccination (PRE)

Notes:

[40] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	42	34	36
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD8 all doubles, PRE	11 (11 to 81)	11 (11 to 61)	11 (11 to 65)	40.5 (11 to 70.5)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),PRE	1 (1 to 44)	1 (1 to 53)	1 (1 to 50)	1 (1 to 42)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),PRE	8 (1 to 116)	57 (1 to 138)	53.5 (1 to 91)	117 (40 to 260)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),PRE	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)

CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),PRE	1 (1 to 64)	1 (1 to 1)	1 (1 to 28)	1 (1 to 14.5)
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),PRE	1 (1 to 40)	1 (1 to 23)	1 (1 to 2)	1 (1 to 1)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	39	39		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD8 all doubles, PRE	11 (11 to 93)	11 (11 to 47)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+IINF-γ (-),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),PRE	1 (1 to 46)	1 (1 to 55)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),PRE	61 (1 to 166)	65 (1 to 302)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),PRE	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),PRE	1 (1 to 1)	1 (1 to 27)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),PRE	1 (1 to 1)	1 (1 to 43)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific

	cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers[41]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

Seven Days after each dose (D7)

Notes:

[41] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	43	37	42
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD8 all doubles, D7	61 (11 to 147)	43 (11 to 101)	11 (11 to 11)	55 (11 to 161)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 31)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),D7	34 (1 to 104)	6 (1 to 116)	3 (1 to 54)	37 (1 to 119)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),D7	61 (1 to 185)	1 (1 to 107)	1 (1 to 61)	161.5 (1 to 574)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),D7	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),D7	6 (1 to 64)	1 (1 to 67)	1 (1 to 85)	7.5 (1 to 72)
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),D7	37 (1 to 89)	1 (1 to 70)	1 (1 to 30)	1 (1 to 50)

End point values	SB692392 1	Control		

	dose + Tritanrix + Prevnar + Polio Sabin Group	Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	44		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD8 all doubles, D7	46 (11 to 82)	11 (11 to 28)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),D7	1 (1 to 100)	1 (1 to 25)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),D7	34 (1 to 303)	123 (1 to 289.5)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),D7	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),D7	1 (1 to 10)	1 (1 to 48)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),D7	1 (1 to 31)	1 (1 to 2.5)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers[42]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

One Month after each dose (M1)

Notes:

[42] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	41	44	34	43
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD8 all doubles, M1	69 (11 to 145)	29.5 (11 to 80)	11 (11 to 28)	82 (11 to 163)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 32)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 32)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),M1	1 (1 to 55)	1 (1 to 52)	2.5 (1 to 85)	1 (1 to 46)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),M1	1 (1 to 12)	1 (1 to 1)	1 (1 to 1)	1 (1 to 28)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),M1	1 (1 to 139)	2.5 (1 to 116)	1 (1 to 48)	142 (1 to 308)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),M1	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),M1	18 (1 to 87)	1 (1 to 50)	1 (1 to 51)	12 (1 to 111)
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),M1	1 (1 to 65)	1 (1 to 5.5)	1 (1 to 5)	1 (1 to 65)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	42		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				

CD8 all doubles, M1	81 (26 to 139)	11 (11 to 53)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),M1	1 (1 to 56)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),M1	11 (1 to 99)	4 (1 to 109)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),M1	109 (2 to 218)	86 (1 to 330)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),M1	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),M1	1 (1 to 90)	1 (1 to 35)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),M1	1 (1 to 64)	1 (1 to 1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers[43]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

Six Months after each dose (M6)

Notes:

[43] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	42	34	40
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD8 all doubles, M6	11 (11 to 53)	11 (11 to 32)	11 (11 to 29)	11 (11 to 20)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+IINF-γ (-),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),M6	1 (1 to 25.5)	1 (1 to 44)	1 (1 to 52)	2 (1 to 65)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),M6	1 (1 to 29.5)	38 (1 to 91)	28 (1 to 67)	27.5 (1 to 60)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),M6	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),M6	1 (1 to 54.5)	1 (1 to 3)	1 (1 to 55.6)	1 (1 to 55.5)
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),M6	1 (1 to 33)	1 (1 to 1)	1 (1 to 1)	1 (1 to 36.5)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	44		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD8 all doubles, M6	11 (11 to 11)	11 (11 to 11)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)		

CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),M6	1 (1 to 63)	2 (1 to 59)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),M6	1 (1 to 56)	1 (1 to 43.5)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),M6	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),M6	1 (1 to 60)	1 (1 to 49)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),M6	1 (1 to 40)	1 (1 to 1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers

End point title	Frequency of M. tuberculosis fusion protein M72 (M72)-specific cluster of differentiation (CD)8+ T cells per million cells expressing at least two different immune markers[44]

End point description:

Immune markers expressed were among Interleukin-2 (IL-2) and/or Interferon-gamma (INF-γ) and/or Tumour necrosis factor-alpha (TNF-α) and/or CD40-ligand (CD40-L).

End point type	Secondary

End point timeframe:

Twelve Months after each dose (M12)

Notes:

[44] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	38	45	33	41
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				

CD8 all doubles, M12	11 (11 to 52)	11 (11 to 38)	11 (11 to 41)	11 (11 to 35)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),M12	1 (1 to 29)	1 (1 to 68)	1 (1 to 32)	1 (1 to 64)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),M12	14.5 (1 to 92)	1 (1 to 59)	1 (1 to 57)	16 (1 to 77)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),M12	1 (1 to 1)	1 (1 to 1)	1 (1 to 5)	1 (1 to 1)
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),M12	1 (1 to 34)	1 (1 to 58)	1 (1 to 117)	1 (1 to 50)
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),M12	1.5 (1 to 67)	1 (1 to 25)	11 (1 to 57)	1 (1 to 48)

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	41	43		
Units: T cells/million cells				
median (inter-quartile range (Q1-Q3))				
CD8 all doubles, M12	11 (11 to 41)	11 (11 to 42)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (+), M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α(+)+INF-γ (-),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(+)+TNF-α (-)+INF-γ (-),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α(+)+INF-γ (-),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(+)+IL-2(-)+TNF-α (-)+INF-γ (-),M12	1 (1 to 35)	1 (1 to 40)		

CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α(+)+INF-γ (-),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (+),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(+)+TNF-α (-)+INF-γ (-),M12	1 (1 to 35)	15 (1 to 66)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ(+),M12	1 (1 to 1)	1 (1 to 1)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (+)+INF-γ (-),M12	1 (1 to 65)	1 (1 to 22)		
CD8.CD40-L(-)+IL-2(-)+TNF-α (-)+INF-γ(+),M12	1 (1 to 128)	1 (1 to 33)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against M72 antigen

End point title	Number of seropositive subjects against M72 antigen[45]

End point description:

A seropositive subject was a subject whose M72 antibody concentration was ≥ 2.8 EL.U/mL.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and after each dose [at 1, 6 and 12 months post-vaccination (M1, M6 and M12)]

Notes:

[45] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	48	39	44
Units: Subjects				
Anti-M72, PRE (N=43,48,39,44,46,46)	0	0	1	0
Anti-M72, M1 (N=42,45,34,43,44,43)	42	39	1	43
Anti-M72, M6 (N=40,45,36,41,45,45)	40	32	0	41
Anti-M72, M12 (N=41,47,35,42,45,43)	41	35	1	42

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio	Control Tritanrix + Prevnar + Polio Sabin Group		

	Sabin Group			
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	46		
Units: Subjects				
Anti-M72, PRE (N=43,48,39,44,46,46)	0	0		
Anti-M72, M1 (N=42,45,34,43,44,43)	39	0		
Anti-M72, M6 (N=40,45,36,41,45,45)	35	1		
Anti-M72, M12 (N=41,47,35,42,45,43)	31	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration of antibodies against M72 antigen

End point title	Concentration of antibodies against M72 antigen[46]

End point description:

A seropositive subject was a subject whose M72 antibody concentration was ≥ 2.8 EL.U/mL.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and after each dose [at 1, 6 and 12 months post-vaccination (M1, M6 and M12)]

Notes:

[46] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	43	48	39	45
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-M72, PRE (N=43,48,39,44,46,46)	1.4 (1.4 to 1.4)	1.4 (1.4 to 1.4)	1.5 (1.3 to 1.7)	1.4 (1.4 to 1.4)
Anti-M72, M1 (N=42,45,34,43,44,43)	1275.2 (981.3 to 1657.2)	8 (6 to 10.7)	1.5 (1.3 to 1.7)	1264 (928 to 1721.5)
Anti-M72, M6 (N=40,45,36,41,45,45)	98.9 (75.2 to 130.1)	4.6 (3.4 to 6.2)	1.4 (1.4 to 1.4)	102.6 (78.7 to 133.9)
Anti-M72, M12 (N=41,47,35,42,45,43)	68.3 (50.7 to 92)	5.3 (3.9 to 7)	1.4 (1.4 to 1.5)	76 (56.6 to 102)

End point values	SB692392 1 dose + Tritanrix +	Control Tritanrix + Prevnar + Polio		

	Prevnar + Polio Sabin Group	Sabin Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	46	46		
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-M72, PRE (N=43,48,39,44,46,46)	1.4 (1.4 to 1.4)	1.4 (1.4 to 1.4)		
Anti-M72, M1 (N=42,45,34,43,44,43)	7.4 (5.3 to 10.2)	1.4 (1.4 to 1.4)		
Anti-M72, M6 (N=40,45,36,41,45,45)	4.9 (3.8 to 6.4)	1.4 (1.4 to 1.5)		
Anti-M72, M12 (N=41,47,35,42,45,43)	4.3 (3.2 to 5.8)	1.5 (1.4 to 1.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against diphtheria toxoid (Anti-D) and tetanus toxoid (Anti-T)

End point title	Number of seroprotected subjects against diphtheria toxoid (Anti-D) and tetanus toxoid (Anti-T)

End point description:

A seroprotected subject was a subject whose anti-diphtheria toxoid (anti-D) antibody concentration was ≥ 0.1 IU/mL.
A seroprotected subject was a subject whose anti-tetanus (anti-T) toxoid antibody concentration was ≥ 0.1 IU/mL.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	43	43	
Units: Subjects				
Anti-D, PRE (N=37,38,38)	6	10	6	
Anti-D,PIII(M3) (N=43,43,43)	43	43	43	
Anti-T, PRE(N=37,38,38)	32	35	35	
Anti-T,PIII(M3) (N=43,43,43)	42	43	43	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-D, Anti-T antibody concentrations

End point title	Anti-D, Anti-T antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	43	43	
Units: IU/mL				
geometric mean (confidence interval 95%)				
Anti-D, PRE (N=37,38,38)	0.1 (0.1 to 0.1)	0.1 (0.1 to 0.1)	0.1 (0.1 to 0.1)	
Anti-D,PIII(M3) (N=43,43,43)	2.1 (1.6 to 2.7)	2.4 (1.8 to 3.1)	2.5 (2 to 3.1)	
Anti-T, PRE(N=37,38,38)	0.6 (0.4 to 1)	1 (0.6 to 1.5)	1 (0.6 to 1.6)	
Anti-T,PIII(M3) (N=43,43,43)	5.5 (4.3 to 7.1)	4.8 (3.6 to 6.4)	6.3 (4.8 to 8.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects against Haemophilus influenza Type B (Anti-PRP)

End point title	Number of seroprotected subjects against Haemophilus influenza Type B (Anti-PRP)

End point description:

A seroprotected subject was a subject whose anti-PRP antibody concentration was ≥0.15 µg/mL.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	46	48	
Units: Subjects				
Anti-PRP, PRE (N=47,46,48)	8	14	12	

Anti-PRP,PIII(M3) (N=44,44,43)	44	44	43	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-PRP antibody concentrations

End point title	Anti-PRP antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	47	46	48	
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PRP, PRE (N=47,46,48)	0.1 (0.1 to 0.1)	0.1 (0.1 to 0.2)	0.1 (0.1 to 0.2)	
Anti-PRP,PIII(M3) (N=44,44,43)	28.2 (20.3 to 39.1)	30.3 (21.8 to 42.1)	31.2 (21.8 to 44.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against B. Pertussis (Anti-BPT)

End point title	Number of seropositive subjects against B. Pertussis (Anti-BPT)

End point description:

A seropositive subject was a subject whose anti-BPT antibody concentration was ≥ 15 EL.U/mL.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	44	43	
Units: Subjects				
Anti-BPT, PRE (N=40,41,43)	1	1	1	
Anti-BPT,PIII(M3) (N=43,44,43)	43	44	43	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-BPT antibody concentrations

End point title	Anti-BPT antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	44	43	
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
Anti-BPT, PRE (N=40,41,43)	7.6 (7.4 to 7.9)	7.7 (7.3 to 8)	7.6 (7.4 to 7.9)	
Anti-BPT,PIII(M3) (N=43,44,43)	132.1 (116.6 to 149.5)	139.4 (117.7 to 164.9)	131.5 (113.5 to 152.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Hepatitis B (Anti-HB)

End point title	Number of seropositive subjects against Hepatitis B (Anti-HB)

End point description:

A seropositive subject was a subject whose anti-HB antibody concentration was ≥ 10 mIU/mL.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	44	43	
Units: Subjects				
Anti-HB, PRE (N=40,41,43)	9	14	13	
Anti-HB,PIII(M3) (N=43,44,43)	42	43	42	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Hepatitis B (Anti-HB) with antibody concentrations ≥100mIU/mL

End point title	Number of seropositive subjects against Hepatitis B (Anti-HB) with antibody concentrations ≥100mIU/mL

End point description:

A decrease in the specificity of the anti-HB ELISA assay had been observed in some studies for low levels of antibody (10-100 mIU/mL). The table shows updated results following partial or complete retesting/reanalysis. Following from this, the table shows data with titers ≥ 100 mIU/mL.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	44	43	
Units: Subjects				
Anti-HB, PRE (N=40,41,43)	2	2	2	
Anti-HB,PIII(M3) (N=43,44,43)	42	42	42	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-HB antibody concentrations

End point title	Anti-HB antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	43	44	43	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-HB, PRE (N=40,41,43)	8.3 (6 to 11.4)	10 (7.1 to 14)	9 (6.7 to 12.2)	
Anti-HB,PIII(M3) (N=43,44,43)	1725.5 (1045 to 2849)	1471.8 (947.5 to 2286)	2153 (1468.2 to 3157.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Polio (Anti-Polio1, Anti-Polio2, Anti-Polio3)

End point title	Number of seropositive subjects against Polio (Anti-Polio1, Anti-Polio2, Anti-Polio3)

End point description:

A seropositive subject was a subject whose anti-polio antibody titer was ≥ 1:8.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	46	45	48	
Units: Subjects				

Anti-Polio1, PRE (N=46,45,48)	36	38	39	
Anti-Polio1, PIII(M3) (N=44,44,43)	41	43	42	
Anti-Polio2,PRE (N=46,45,48)	33	32	38	
Anti-Polio2,PIII(M3) (N=44,44,43)	43	42	42	
Anti-Polio3,PRE (N=46,45,48)	21	18	14	
Anti-Polio3,PIII(M3) (N=44,44,43)	42	38	39	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-Polio1, Anti-Polio2, Anti-Polio3 antibody concentrations

End point title	Anti-Polio1, Anti-Polio2, Anti-Polio3 antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	46	45	48	
Units: Titer				
geometric mean (confidence interval 95%)				
Anti-Polio1, PRE (N=46,45,48)	56.3 (30.7 to 103.2)	48.8 (27.3 to 87.5)	103.8 (58.1 to 185.3)	
Anti-Polio1, PIII(M3) (N=44,44,43)	299.9 (167.6 to 536.7)	397.8 (240.2 to 658.8)	573.1 (368.7 to 890.6)	
Anti-Polio2,PRE (N=46,45,48)	51.8 (28.8 to 93.2)	53.2 (28 to 101)	61.2 (34.8 to 107.8)	
Anti-Polio2,PIII(M3) (N=44,44,43)	458.7 (307.7 to 683.7)	524.3 (331.1 to 830.3)	499.9 (317.7 to 786.5)	
Anti-Polio3,PRE (N=46,45,48)	15.2 (9 to 25.6)	15.4 (8.6 to 27.6)	10.9 (6.7 to 17.9)	
Anti-Polio3,PIII(M3) (N=44,44,43)	154.8 (100.8 to 237.8)	103.5 (59.7 to 179.6)	123 (73.6 to 205.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects against Streptococcus pneumoniae

(Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F)	
End point title	Number of seropositive subjects against Streptococcus pneumoniae (Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F)

End point description:

A seropositive subject was a subject whose anti-S pneumoniae antibody concentration was ≥ 0.05 µg/mL.

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	43	43	
Units: Subjects				
Anti-4, PRE (N=39,39,40)	18	21	12	
Anti-4, PIII(M3) (N=43,43,43)	43	43	43	
Anti-6B,PRE (N=38,39,43)	29	27	26	
Anti-6B,PIII(M3) (N=44,43,43)	44	41	40	
Anti-9V,PRE (N=37,39,39)	28	33	25	
Anti-9V,PIII(M3) (N=43,43,43)	43	43	43	
Anti-14,PRE (N=39,38,40)	39	38	38	
Anti-14,PIII(M3) (N=44,44,43)	44	44	43	
Anti-18C, PRE (N=42,40,42)	30	35	26	
Anti-18C, PIII(M3) (N=43,44,43)	43	44	43	
Anti-19F, PRE (N=37,38,40)	35	37	39	
Anti-19F, PIII(M3) (N=44,44,43)	44	44	43	
Anti-23F,PRE (N=41,40,42)	25	30	26	
Anti-23F, PIII(M3) (N=44,43,43)	43	43	42	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects against Streptococcus pneumoniae (Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F) with antibody concentrations ≥ 0.2 µg/mL

End point title	Number of subjects against Streptococcus pneumoniae (Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F) with antibody concentrations ≥ 0.2 µg/mL

End point description:

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	44	43	
Units: Subjects				
Anti-4, PRE (N=39,39,40)	5	10	2	
Anti-4, PIII(M3) (N=43,43,43)	43	43	43	
Anti-6B,PRE (N=38,39,43)	8	5	6	
Anti-6B,PIII(M3) (N=44,43,43)	38	40	35	
Anti-9V,PRE (N=37,39,39)	18	20	10	
Anti-9V,PIII(M3) (N=43,43,43)	43	43	43	
Anti-14,PRE (N=39,38,40)	34	33	33	
Anti-14,PIII(M3) (N=44,44,43)	44	43	43	
Anti-18C, PRE (N=42,40,42)	10	17	9	
Anti-18C, PIII(M3) (N=43,44,43)	43	43	42	
Anti-19F, PRE (N=37,38,40)	30	30	26	
Anti-19F, PIII(M3) (N=44,44,43)	43	44	43	
Anti-23F,PRE (N=41,40,42)	9	11	14	
Anti-23F, PIII(M3) (N=44,43,43)	42	41	42	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F antibody concentrations

End point title	Anti-4, Anti-6B, Anti-9V, Anti-14, Anti-18C, Anti-19F, Anti-23F antibody concentrations

End point description:

End point type	Secondary

End point timeframe:

Before vaccination (PRE) and 1 Month post Dose 3 [PIII(M3)]

End point values	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	44	44	43	
Units: µg/mL				

geometric mean (confidence interval 95%)				
Anti-4, PRE (N=39,39,40)	0.1 (0 to 0.1)	0.1 (0.1 to 0.1)	0 (0 to 0)	
Anti-4, PIII(M3) (N=43,43,43)	7.7 (6.2 to 9.7)	6.4 (5.3 to 7.8)	8.1 (6.5 to 10)	
Anti-6B,PRE (N=38,39,43)	0.1 (0.1 to 0.1)	0.1 (0.1 to 0.1)	0.1 (0.1 to 0.1)	
Anti-6B,PIII(M3) (N=44,43,43)	2.3 (1.4 to 3.8)	1.5 (0.9 to 2.4)	1.5 (0.8 to 2.7)	
Anti-9V,PRE (N=37,39,39)	0.1 (0.1 to 0.2)	0.2 (0.1 to 0.3)	0.1 (0.1 to 0.1)	
Anti-9V,PIII(M3) (N=43,43,43)	5.8 (4.4 to 7.7)	4.1 (3 to 5.6)	6 (4.5 to 8.1)	
Anti-14,PRE (N=39,38,40)	0.8 (0.6 to 1.2)	1.1 (0.7 to 1.6)	0.7 (0.4 to 1)	
Anti-14,PIII(M3) (N=44,44,43)	3.6 (2.5 to 5.3)	3.3 (2.3 to 4.7)	4.2 (2.8 to 6.2)	
Anti-18C, PRE (N=42,40,42)	0.1 (0.1 to 0.1)	0.2 (0.1 to 0.2)	0.1 (0.1 to 0.1)	
Anti-18C, PIII(M3) (N=43,44,43)	7.2 (5.7 to 9)	5.1 (3.8 to 7)	6.1 (4.2 to 8.8)	
Anti-19F, PRE (N=37,38,40)	0.4 (0.3 to 0.6)	0.5 (0.3 to 0.7)	0.3 (0.2 to 0.5)	
Anti-19F, PIII(M3) (N=44,44,43)	5.8 (4.1 to 8.2)	5.4 (4.2 to 6.9)	5.9 (4.5 to 7.5)	
Anti-23F,PRE (N=41,40,42)	0.1 (0.1 to 0.1)	0.1 (0.1 to 0.1)	0.1 (0.1 to 0.1)	
Anti-23F, PIII(M3) (N=44,43,43)	3.2 (2.1 to 4.8)	3 (2 to 4.6)	3.8 (2.5 to 5.7)	

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)[47]

End point description:

End point type	Secondary

End point timeframe:

During the entire study period

Notes:

[47] - 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 reported per sets of groups, based on reporting timepoints (post first, second, third dose etc.)

End point values	SB692342 2 dose Group	SB692342 1 dose Group	Control Menjugate Group	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	50	50	49
Units: Subjects				
Any SAEs	2	3	3	1

End point values	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	52	49		
Units: Subjects				
Any SAEs	1	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited symptoms during the 7-day post-vaccination period, Unsolicited AEs during the 30-day post-vaccination period, SAEs up till one Month post vaccination and during the entire period

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	14.1

Reporting groups

Reporting group title	SB692342 2 dose Group
Reporting group description: -	
Reporting group title	SB692392 1 dose Group
Reporting group description: -	
Reporting group title	Control Menjugate Group
Reporting group description: -	
Reporting group title	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	
Reporting group title	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group
Reporting group description: -	
Reporting group title	Control Tritanrix + Prevnar + Polio Sabin Group

Reporting group description: -

Serious adverse events	SB692342 2 dose Group	SB692392 1 dose Group	Control Menjugate Group
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 50 (4.00%)	3 / 50 (6.00%)	3 / 50 (6.00%)
number of deaths (all causes)	0	0	1
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Thermal burn			
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
Nervous system disorders			
Febrile convulsion			
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
General disorders and administration site conditions			

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 / 0
Skin and subcutaneous tissue disorders			
Rash			
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
Infections and infestations			
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 / 1
Bronchopneumonia			
subjects affected / exposed	2 / 50 (4.00%)	1 / 50 (2.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	1 / 50 (2.00%)	1 / 50 (2.00%)	0 / 50 (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
Cerebral malaria			
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
Malaria			
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

Serious adverse events	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 49 (2.04%)	1 / 52 (1.92%)	1 / 49 (2.04%)

number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Thermal burn			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 49 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Febrile convulsion			
subjects affected / exposed	0 / 49 (0.00%)	1 / 52 (1.92%)	0 / 49 (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
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 49 (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
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 49 (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			
Sepsis			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	1 / 49 (2.04%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 49 (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			
subjects affected / exposed	1 / 49 (2.04%)	0 / 52 (0.00%)	0 / 49 (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

Cerebral malaria			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 49 (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
Malaria			
subjects affected / exposed	0 / 49 (0.00%)	0 / 52 (0.00%)	0 / 49 (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	SB692342 2 dose Group	SB692392 1 dose Group	Control Menjugate Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 50 (56.00%)	27 / 50 (54.00%)	26 / 50 (52.00%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed[1]	3 / 50 (6.00%)	1 / 50 (2.00%)	4 / 50 (8.00%)
occurrences (all)	3	1	4
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[2]	6 / 50 (12.00%)	2 / 50 (4.00%)	6 / 50 (12.00%)
occurrences (all)	6	2	6
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	0 / 50 (0.00%)	0 / 50 (0.00%)	0 / 50 (0.00%)
occurrences (all)	0	0	0
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed[4]	2 / 50 (4.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	2	0	1
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed[5]	3 / 50 (6.00%)	0 / 50 (0.00%)	2 / 50 (4.00%)
occurrences (all)	3	0	2

Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed[6]	3 / 50 (6.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	3	0	1
Temperature(Axilarry)			
alternative assessment type: Systematic			
subjects affected / exposed[7]	19 / 50 (38.00%)	5 / 50 (10.00%)	13 / 50 (26.00%)
occurrences (all)	19	5	13
Eye disorders			
Conjunctivitis			
subjects affected / exposed[8]	0 / 50 (0.00%)	0 / 50 (0.00%)	1 / 50 (2.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed[9]	8 / 50 (16.00%)	5 / 50 (10.00%)	2 / 50 (4.00%)
occurrences (all)	8	5	2
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed[10]	21 / 50 (42.00%)	14 / 50 (28.00%)	19 / 50 (38.00%)
occurrences (all)	21	14	19

Non-serious adverse events	SB692392 2dose + Tritanrix + Prevnar + Polio Sabin Group	SB692392 1 dose + Tritanrix + Prevnar + Polio Sabin Group	Control Tritanrix + Prevnar + Polio Sabin Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 49 (51.02%)	14 / 52 (26.92%)	22 / 49 (44.90%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed[1]	0 / 47 (0.00%)	2 / 52 (3.85%)	0 / 48 (0.00%)
occurrences (all)	0	2	0
Pain			
alternative assessment type: Systematic			
subjects affected / exposed[2]	10 / 47 (21.28%)	13 / 52 (25.00%)	13 / 48 (27.08%)
occurrences (all)	10	13	13
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed[3]	6 / 47 (12.77%)	8 / 52 (15.38%)	8 / 48 (16.67%)
occurrences (all)	6	8	8

Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed[4]	3 / 47 (6.38%)	3 / 52 (5.77%)	0 / 48 (0.00%)
occurrences (all)	3	3	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed[5]	8 / 47 (17.02%)	5 / 52 (9.62%)	4 / 48 (8.33%)
occurrences (all)	8	5	4
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed[6]	3 / 47 (6.38%)	2 / 52 (3.85%)	0 / 48 (0.00%)
occurrences (all)	3	2	0
Temperature(Axilarry)			
alternative assessment type: Systematic			
subjects affected / exposed[7]	18 / 47 (38.30%)	9 / 52 (17.31%)	12 / 48 (25.00%)
occurrences (all)	18	9	12
Eye disorders			
Conjunctivitis			
subjects affected / exposed[8]	0 / 47 (0.00%)	0 / 52 (0.00%)	3 / 48 (6.25%)
occurrences (all)	0	0	3
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed[9]	5 / 47 (10.64%)	1 / 52 (1.92%)	3 / 48 (6.25%)
occurrences (all)	5	1	3
Infections and infestations			
Respiratory tract infection			
subjects affected / exposed[10]	15 / 47 (31.91%)	9 / 52 (17.31%)	14 / 48 (29.17%)
occurrences (all)	15	9	14

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: The analysis was performed on the Total Vaccinated cohort, on subjects with at least one administered dose with safety follow-up.
[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.
[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.

[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.
[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.
[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.
[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: The analysis was performed on the Total Vaccinated cohort, only on subjects with their symptom sheets completed.
[8] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.
Justification: The analysis was performed on the Total Vaccinated cohort, on subjects with at least one administered dose with safety follow-up.
[9] - 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: The analysis was performed on the Total Vaccinated cohort, on subjects with at least one administered dose with safety follow-up.
[10] - 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: The analysis was performed on the Total Vaccinated cohort, on subjects with at least one administered dose with safety follow-up.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
19 November 2010	The purpose of this amendment is to apply a standard and robust methodology for the collection, documentation and safety monitoring of serious and nonserious potential immune mediated disorders (pIMDs) as adverse events of special interest occurring in subjects participating in clinical trials evaluating GSK adjuvant containing vaccines. Guidance for what is considered as to be potentially immune mediated and time period of pIMD reporting are included in this amendment.
28 July 2011	The pneumococcal conjugate vaccine (PCV) being administered as part of the EPI vaccination in this study is Prevnar (7-valent PCV). The manufacturing company (Wyeth) has stopped production and marketing of 7-valent PCV which was initially used in the study. It currently produces and markets the 13-valent PCV (Prevnar 13). The SPC shows that the 13-valent PCV can be given after the 7-valent PCV with no safety issues. Hence for the booster dose, subjects in this study will be given the 13- valent PCV. This change in formulation of the administered vaccine is not expected to have an impact on the analysis of any study endpoints. The protocol has been amended to include a description of the 13-valent PCV.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported