Clinical trial results:
A Phase 2, randomised, observer-blind, controlled, multi country study to assess the safety and immunogenicity of a single intramuscular dose of GSK Biologicals' investigational recombinant chimpanzee adenovirus Type 3-vectored Ebola Zaire vaccine (ChAd3-EBO-Z) (GSK3390107A), in children 1 to 17 years of age in Africa

Summary

EudraCT number	2014-004714-28
Trial protocol	Outside EU/EEA
Global end of trial date	15 May 2017

Results information

Result version number	v1 (current)
This version publication date	11 May 2019
First version publication date	11 May 2019

Trial information

Trial identification

Sponsor protocol code	202090

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02548078
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	03 July 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 May 2017
Global end of trial reached?	Yes
Global end of trial date	15 May 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and reactogenicity of a single IM dose of the ChAd3 EBO-Z vaccine, overall and in children aged 1 to 5, 6 to 12, and 13 to 17 years, separately.

Protection of trial subjects:

The vaccine/ product recipients were to be observed closely for at least 30 minutes with appropriate medical treatment readily available in case of a rare anaphylactic reaction following the administration of vaccine(s)/ product(s).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 October 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Mali: 515
Country: Number of subjects enrolled	Senegal: 85
Worldwide total number of subjects	600
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)	0
Children (2-11 years)	400
Adolescents (12-17 years)	200
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: from 776 subjects enrolled in the study, 176 subjects were screen failures and were withdrawn from the study.

Period 1

Period 1 title	Overall Study (baseline) (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Assessor

Blinding implementation details:

Observer-blind from study start until the interim analysis that was conducted when safety, reactogenicity and immunogenicity (including at least anti-GP EBOV data at Day 30) data were available from all subjects up to 30 days after vaccination at Day 0. By observer-blind, it is meant that the vaccine recipient and those responsible for the evaluation of any study endpoint will all be unaware of which vaccine was administered.
Single-blind as of the interim analysis at Day 30.

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK3390107A+Nimenrix Group

Arm description:

Subjects in the GSK3390107A+Nimenrix Group received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the deltoid region, or thigh region for smaller children.

Arm type	Active comparator
Investigational medicinal product name	GSK134612A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 0

Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Month 6

Arm title	Nimenrix+GSK3390107A Group

Arm description:

Subjects in the Nimenrix+GSK3390107A Group received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the deltoid region, or thigh region for smaller children.

Arm type	Other

Investigational medicinal product name	Nimenrix
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Day 0

Investigational medicinal product name	GSK134612A
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose at Month 6

Number of subjects in period 1	GSK3390107A+Nimenrix Group	Nimenrix+GSK3390107A Group
Started	300	300
Completed	295	294
Not completed	5	6
Moved from study area	3	3
Serious adverse event/Adverse event	1	-
Lost to follow-up	1	3

Baseline characteristics

Reporting groups	
Reporting group title	GSK3390107A+Nimenrix Group
Reporting group description:	
Subjects in the GSK3390107A+Nimenrix Group received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the deltoid region, or thigh region for smaller children.	
Reporting group title	Nimenrix+GSK3390107A Group
Reporting group description:	
Subjects in the Nimenrix+GSK3390107A Group received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the deltoid region, or thigh region for smaller children.	

Reporting group values	GSK3390107A+Nimenrix Group	Nimenrix+GSK3390107A Group	Total
Number of subjects	300	300	600
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	200	200	400
Adolescents (12-17 years)	100	100	200
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	9.0	8.8	
standard deviation	± 4.95	± 5.03	-
Gender categorical Units: Subjects			
Female	149	150	299
Male	151	150	301
Race/Ethnicity, Customized Units: Subjects			
African heritage/ African American	300	300	600

Subject analysis sets	
Subject analysis set title	GSK3390107A+Nimenrix 13-17YOA Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Sub-group of subjects from the GSK3390107A+Nimenrix Group, between and including 13 to 17 years of age (YOA), who received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the deltoid region.	
Subject analysis set title	Nimenrix+GSK3390107A 13-17YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the Nimenrix+GSK3390107A Group, between and including 13 to 17 years of age (YOA), who received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the deltoid region.

Subject analysis set title	GSK3390107A+Nimenrix 6-12YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the GSK3390107A+Nimenrix Group, between and including 6 to 12 years of age (YOA), who received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the thigh region.

Subject analysis set title	Nimenrix+GSK3390107A 6-12YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the Nimenrix+GSK3390107A Group, between and including 6 to 12 years of age (YOA), who received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the thigh region.

Subject analysis set title	GSK3390107A+Nimenrix 1-5YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the GSK3390107A+Nimenrix Group, between and including 1 to 5 years of age (YOA), who received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the thigh region.

Subject analysis set title	Nimenrix+GSK3390107A 1-5YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the Nimenrix+GSK3390107A Group, between and including 1 to 5 years of age (YOA), who received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the thigh region.

Reporting group values	GSK3390107A+Nimenrix 13-17YOA Group	Nimenrix+GSK3390107A 13-17YOA Group	GSK3390107A+Nimenrix 6-12YOA Group
Number of subjects	100	100	99
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	99
Adolescents (12-17 years)	100	100	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	12	8	6
standard deviation	±	±	±
Gender categorical Units: Subjects			
Female	54	54	45
Male	46	46	54

Race/Ethnicity, Customized Units: Subjects			
African heritage/ African American	100	100	99

Reporting group values	Nimenrix+GSK3390107A 6-12YOA Group	GSK3390107A+Nimenrix 1-5YOA Group	Nimenrix+GSK3390107A 1-5YOA Group
Number of subjects	101	101	99
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	101	101	99
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	10	23	6
standard deviation	±	±	±
Gender categorical Units: Subjects			
Female	48	50	48
Male	53	51	51
Race/Ethnicity, Customized Units: Subjects			
African heritage/ African American	101	101	99

End points

End points reporting groups

Reporting group title	GSK3390107A+Nimenrix Group

Reporting group description:

Subjects in the GSK3390107A+Nimenrix Group received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the deltoid region, or thigh region for smaller children.

Reporting group title	Nimenrix+GSK3390107A Group

Reporting group description:

Subjects in the Nimenrix+GSK3390107A Group received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the deltoid region, or thigh region for smaller children.

Subject analysis set title	GSK3390107A+Nimenrix 13-17YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the GSK3390107A+Nimenrix Group, between and including 13 to 17 years of age (YOA), who received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the deltoid region.

Subject analysis set title	Nimenrix+GSK3390107A 13-17YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the Nimenrix+GSK3390107A Group, between and including 13 to 17 years of age (YOA), who received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the deltoid region.

Subject analysis set title	GSK3390107A+Nimenrix 6-12YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the GSK3390107A+Nimenrix Group, between and including 6 to 12 years of age (YOA), who received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the thigh region.

Subject analysis set title	Nimenrix+GSK3390107A 6-12YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the Nimenrix+GSK3390107A Group, between and including 6 to 12 years of age (YOA), who received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the thigh region.

Subject analysis set title	GSK3390107A+Nimenrix 1-5YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the GSK3390107A+Nimenrix Group, between and including 1 to 5 years of age (YOA), who received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the thigh region.

Subject analysis set title	Nimenrix+GSK3390107A 1-5YOA Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Sub-group of subjects from the Nimenrix+GSK3390107A Group, between and including 1 to 5 years of age (YOA), who received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the thigh region.

Primary: Number of subjects with solicited local symptoms, overall

End point title	Number of subjects with solicited local symptoms, overall[1]

End point description:

Assessed solicited local symptoms included: pain and swelling at the injections site. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = crying at limb movement/spontaneous pain.Grade 3 swelling = swelling extending on a surface higher than (>) 30 millimeters (mm). Solicited

symptoms, for this endpoint, were assessed in all subjects, in both groups.

End point type	Primary

End point timeframe:

During a 7-day follow-up period after each vaccination (i.e. the day of vaccination and 6 subsequent days)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Participants				
Any Pain	127	60		
Grade 3 Pain	4	0		
Any Swelling	5	1		
Grade 3 Swelling	1	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited local symptoms, by age stratum

End point title	Number of subjects with solicited local symptoms, by age stratum[2]

End point description:

Assessed solicited local symptoms included: pain and swelling at the injections site. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = crying at limb movement/spontaneous pain.Grade 3 swelling = swelling extending on a surface higher than (>) 30 millimeters (mm), for children between 1-5 years old; > 50 mm for children between 6-12 years old and >100 mm for children between 13-17 years old.

End point type	Primary

End point timeframe:

During a 7-day follow-up period after each vaccination (i.e. the day of vaccination and 6 subsequent days)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	99	101
Units: Participants				
Any Pain	31	14	41	23
Grade 3 Pain	0	0	1	0
Any Swelling	1	0	3	1
Grade 3 Swelling	0	0	1	0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	101	99		
Units: Participants				
Any Pain	55	23		
Grade 3 Pain	3	0		
Any Swelling	1	0		
Grade 3 Swelling	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited general symptoms, overall

End point title	Number of subjects with solicited general symptoms, overall[3]

End point description:

Solicited general symptoms assessed included: fatigue, fever [defined as axillary temperature equal to or above (≥) 37.5 degrees Celsius (°C)], gastrointestinal symptoms [nausea, vomiting, diarrhoea and/or abdominal pain], headache, drowsiness, irritability/fussiness and loss of appetite. Any = occurrence of the symptom regardless of intensity grade. Grade 3 fatigue/headache/drowsiness/gastrointestinal symptoms = fatigue/headache/drowsiness/gastrointestinal symptoms that prevented normal activity. Grade 3 fever = temperature > 39.5°C. Grade 3 irritability/fussiness = crying that couldn't be comforted. Grade 3 loss of appetite = not eating at all. Related = symptom assessed by the investigator as related to the vaccination. Solicited general symptoms, for this endpoint, were assessed in all subjects, in both groups.

End point type	Primary

End point timeframe:

During a 7-day follow-up period after each vaccination (i.e. the day of vaccination and 6 subsequent days)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Participants				
Any Fatigue	33	6		
Grade 3 Fatigue	0	0		
Related Fatigue	32	5		
Any Fever	95	28		
Grade 3 Fever	1	0		
Related Fever	89	26		
Any Gastrointestinal symptoms	16	6		
Grade 3 Gastrointestinal symptoms	0	0		

Related Gastrointestinal symptoms	13	3		
Any Headache	62	17		
Grade 3 Headache	0	0		
Related Headache	60	14		
Any Drowsiness	26	2		
Grade 3 Drowsiness	3	0		
Related Drowsiness	26	1		
Any Irritability/fussiness	10	2		
Grade 3 Irritability/fussiness	4	0		
Related Irritability/fussiness	10	2		
Any Loss of appetite	24	4		
Grade 3 Loss of appetite	3	0		
Related Loss of appetite	24	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited general symptoms, by age stratum

End point title	Number of subjects with solicited general symptoms, by age stratum[4]

End point description:

Solicited general symptoms assessed included: fatigue, fever [defined as axillary temperature equal to or above (≥) 37.5 degrees Celsius (°C)], gastrointestinal symptoms [nausea, vomiting, diarrhoea and/or abdominal pain], headache, drowsiness, irritability/fussiness and loss of appetite. Any = occurrence of the symptom regardless of intensity grade. Grade 3 fatigue/headache/drowsiness/gastrointestinal symptoms = fatigue/headache/drowsiness/gastrointestinal symptoms that prevented normal activity. Grade 3 fever = temperature > 39.5°C. Grade 3 irritability/fussiness = crying that couldn't be comforted. Grade 3 loss of appetite = not eating at all. Related = symptom assessed by the investigator as related to the vaccination. Solicited general symptoms, for this endpoint, were assessed in subjects aged 1-5 years, 6-12 years and 13-17
years. Symptoms with no values were not assessed for those specific age groups.

End point type	Primary

End point timeframe:

During a 7-day follow-up period after each vaccination (i.e. the day of vaccination and 6 subsequent days)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	99	101
Units: Participants				
Any Fatigue	20	5	13	1
Grade 3 Fatigue	0	0	0	0
Related Fatigue	20	4	12	1
Any Fever	20	4	25	1
Grade 3 Fever	0	0	0	0
Related Fever	17	4	23	1

Any Gastrointestinal symptoms	9	2	7	4
Grade 3 Gastrointestinal symptoms	0	0	0	0
Related Gastrointestinal symptoms	8	0	5	3
Any Headache	36	11	26	6
Grade 3 Headache	0	0	0	0
Related Headache	35	8	25	6
Any Drowsiness	0	0	0	0
Grade 3 Drowsiness	0	0	0	0
Related Drowsiness	0	0	0	0
Any Irritability/fusiness	0	0	0	0
Grade 3 Irritability/fusiness	0	0	0	0
Related Irritability/fusiness	0	0	0	0
Any Loss of appetite	0	0	0	0
Grade 3 Loss of appetite	0	0	0	0
Related Loss of appetite	0	0	0	0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	101	99		
Units: Participants				
Any Fatigue	0	0		
Grade 3 Fatigue	0	0		
Related Fatigue	0	0		
Any Fever	50	23		
Grade 3 Fever	1	0		
Related Fever	49	21		
Any Gastrointestinal symptoms	0	0		
Grade 3 Gastrointestinal symptoms	0	0		
Related Gastrointestinal symptoms	0	0		
Any Headache	0	0		
Grade 3 Headache	0	0		
Related Headache	0	0		
Any Drowsiness	26	2		
Grade 3 Drowsiness	3	0		
Related Drowsiness	26	1		
Any Irritability/fusiness	10	2		
Grade 3 Irritability/fusiness	4	0		
Related Irritability/fusiness	10	2		
Any Loss of appetite	24	4		
Grade 3 Loss of appetite	3	0		
Related Loss of appetite	24	4		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with unsolicited adverse events (AEs), overall

End point title	Number of subjects with unsolicited adverse events (AEs), overall[5]

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Unsolicited adverse events, for this endpoint, were assessed in all subjects, in both groups.

End point type	Primary

End point timeframe:

During the 30-day follow-up period after each vaccination (i.e. the day of vaccination and 29 subsequent days)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Participants	41	24		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with unsolicited adverse events (AEs), by age stratum

End point title	Number of subjects with unsolicited adverse events (AEs), by age stratum[6]

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Unsolicited AEs, for this endpoint, were assessed in subjects between 1-5 years of age, 6-12 years of age and 13-17 years of age.

End point type	Primary

End point timeframe:

During the 30-day follow-up period after each vaccination (i.e. the day of vaccination and 29 subsequent days)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	99	101
Units: Participants	12	8	6	10

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	101	99		
Units: Participants	23	6		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, overall

End point title	Percentage of subjects with haematological laboratory abnormalities, overall[7]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Screening.

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	257	258		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	3.9	2.7		
RBC, Normal	84.4	81.8		
RBC, High	11.7	15.5		
Neutrophils, Low	12.8	10.9		
Neutrophils, Normal	86.4	89.1		
Neutrophils, High	0.8	0		
Lymphocytes, Low	1.6	0		
Lymphocytes, Normal	97.3	97.3		
Lymphocytes, High	1.2	2.7		

WBC, Low	3.5	1.2		
WBC, Normal	94.9	97.3		
WBC, High	1.6	1.6		
Haemoglobin, Low	33.5	32.9		
Haemoglobin, Normal	66.1	67.1		
Haemoglobin, High	0.4	0		
Platelets, Low	1.2	1.2		
Platelets, Normal	80.2	77.5		
Platelets, High	18.7	21.3		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, by age stratum

End point title	Percentage of subjects with haematological laboratory abnormalities, by age stratum[8]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Screening

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	89	91
Units: Percentage of participants				
number (not applicable)				
RBC, Low	7.0	5.0	1.1	1.1
RBC, Normal	80.0	81.0	84.3	78.0
RBC, High	13.0	14.0	14.6	20.9
Neutrophils, Low	28.0	20.0	0	4.4
Neutrophils, Normal	72.0	80.0	97.8	95.6
Neutrophils, High	0	0	2.2	0
Lymphocytes, Low	0	0	0	0
Lymphocytes, Normal	98.0	95.0	100.0	97.8
Lymphocytes, High	2.0	5.0	0	2.2
WBC, Low	3.0	0	0	0
WBC, Normal	95.0	97.0	98.9	98.9
WBC, High	2.0	3.0	1.1	1.1
Haemoglobin, Low	38.0	36.0	14.6	14.3

Haemoglobin, Normal	62.0	64.0	85.4	85.7
Haemoglobin, High	0	0	0	0
Platelets, Low	0	0	0	0
Platelets, Normal	74.0	71.0	80.9	78.0
Platelets, High	26.0	29.0	19.1	22.0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	67		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	2.9	1.5		
RBC, Normal	91.2	88.1		
RBC, High	5.9	10.4		
Neutrophils, Low	7.4	6.0		
Neutrophils, Normal	92.6	94.0		
Neutrophils, High	0	0		
Lymphocytes, Low	5.9	0		
Lymphocytes, Normal	92.6	100.0		
Lymphocytes, High	1.5	0		
WBC, Low	8.8	4.5		
WBC, Normal	89.7	95.5		
WBC, High	1.5	0		
Haemoglobin, Low	51.5	53.7		
Haemoglobin, Normal	47.1	46.3		
Haemoglobin, High	1.5	0		
Platelets, Low	4.4	4.5		
Platelets, Normal	88.2	86.6		
Platelets, High	7.4	9.0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, overall

End point title	Percentage of subjects with haematological laboratory abnormalities, overall[9]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 3

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	257	256		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	5.1	6.3		
RBC, Normal	86.8	82.4		
RBC, High	8.2	11.3		
Neutrophils, Low	28.4	11.7		
Neutrophils, Normal	71.2	88.3		
Neutrophils, High	0.4	0		
Lymphocytes, Low	0.8	0		
Lymphocytes, Normal	98.4	99.2		
Lymphocytes, High	0.8	0.8		
WBC, Low	7.8	2.3		
WBC, Normal	90.7	96.1		
WBC, High	1.6	1.6		
Haemoglobin, Low	41.2	46.1		
Haemoglobin, Normal	58.8	53.1		
Haemoglobin, High	0	0.8		
Platelets, Low	0.8	1.2		
Platelets, Normal	87.5	82.4		
Platelets, High	11.7	16.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, by age stratum

End point title	Percentage of subjects with haematological laboratory abnormalities, by age stratum[10]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 3

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	89	91
Units: Percentage of participants				
number (not applicable)				
RBC, Low	6.0	9.0	2.2	4.4
RBC, Normal	82.0	80.0	89.9	82.4
RBC, High	12.0	11.0	7.9	13.2
Neutrophils, Low	47.0	22.0	14.6	4.4
Neutrophils, Normal	53.0	78.0	85.4	95.6
Neutrophils, High	0	0	0	0
Lymphocytes, Low	0	0	0	0
Lymphocytes, Normal	99.0	99.0	100.0	98.9
Lymphocytes, High	1.0	1.0	0	1.1
WBC, Low	6.0	2.0	4.5	2.2
WBC, Normal	92.0	94.0	95.5	97.8
WBC, High	2.0	4.0	0	0
Haemoglobin, Low	43.0	44.0	23.6	33.0
Haemoglobin, Normal	57.0	56.0	76.4	67.0
Haemoglobin, High	0	0	0	0
Platelets, Low	0	0	0	0
Platelets, Normal	79.0	77.0	93.3	84.6
Platelets, High	21.0	23.0	6.7	15.4

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	65		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	7.4	4.6		
RBC, Normal	89.7	86.2		
RBC, High	2.9	9.2		
Neutrophils, Low	19.1	6.2		
Neutrophils, Normal	79.4	93.8		
Neutrophils, High	1.5	0		
Lymphocytes, Low	2.9	0		
Lymphocytes, Normal	95.6	100.0		
Lymphocytes, High	1.5	0		
WBC, Low	14.7	3.1		
WBC, Normal	82.4	96.9		
WBC, High	2.9	0		
Haemoglobin, Low	61.8	67.7		
Haemoglobin, Normal	61.8	67.7		
Haemoglobin, High	0	3.1		
Platelets, Low	2.9	4.6		
Platelets, Normal	92.6	87.7		

Platelets, High	4.4	7.7		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, overall

End point title	Percentage of subjects with haematological laboratory abnormalities, overall[11]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 6

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	256	256		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	7.0	5.5		
RBC, Normal	83.6	84.0		
RBC, High	9.4	10.5		
Neutrophils, Low	19.9	14.8		
Neutrophils, Normal	79.3	84.8		
Neutrophils, High	0.8	0.4		
Lymphocytes, Low	1.2	0.8		
Lymphocytes, Normal	97.7	97.3		
Lymphocytes, High	1.2	2.0		
WBC, Low	4.7	2.0		
WBC, Normal	94.1	96.5		
WBC, High	1.2	1.6		
Haemoglobin, Low	42.6	44.1		
Haemoglobin, Normal	57.4	55.1		
Haemoglobin, High	0	0.8		
Platelets, Low	2.3	2.0		
Platelets, Normal	79.7	77.3		
Platelets, High	18.0	20.7		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, by age stratum

End point title	Percentage of subjects with haematological laboratory abnormalities, by age stratum[12]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 6

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	99	98	89	91
Units: Percentage of participants				
number (not applicable)				
RBC, Low	12.1	8.2	2.2	3.3
RBC, Normal	74.4	82.7	88.8	82.4
RBC, High	13.1	9.2	9.0	14.3
Neutrophils, Low	37.4	29.6	6.7	6.6
Neutrophils, Normal	61.6	69.4	92.1	93.4
Neutrophils, High	1.0	1.0	1.1	0
Lymphocytes, Low	1.0	0	0	0
Lymphocytes, Normal	97.0	95.9	98.9	98.9
Lymphocytes, High	2.0	4.1	1.1	1.1
WBC, Low	5.1	1.0	0	1.1
WBC, Normal	91.9	94.9	100.0	98.9
WBC, High	3.0	4.1	0	0
Haemoglobin, Low	50.5	40.8	22.5	36.3
Haemoglobin, Normal	49.5	59.2	77.5	63.7
Haemoglobin, High	0	0	0	0
Platelets, Low	0	0	0	0
Platelets, Normal	71.7	71.4	83.1	80.2
Platelets, High	28.3	28.6	16.9	19.8

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	67		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	5.9	4.5		
RBC, Normal	89.7	88.1		
RBC, High	4.4	7.5		
Neutrophils, Low	11.8	4.5		
Neutrophils, Normal	88.2	95.5		
Neutrophils, High	0	0		
Lymphocytes, Low	2.9	3.0		
Lymphocytes, Normal	97.1	97.0		
Lymphocytes, High	0	0		
WBC, Low	10.3	4.5		
WBC, Normal	89.7	95.5		
WBC, High	0	0		
Haemoglobin, Low	57.4	59.7		
Haemoglobin, Normal	42.6	37.3		
Haemoglobin, High	0	3.0		
Platelets, Low	8.8	7.5		
Platelets, Normal	86.8	82.1		
Platelets, High	4.4	10.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, overall

End point title	Percentage of subjects with haematological laboratory abnormalities, overall[13]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 30

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	257	256		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	4.7	3.5		
RBC, Normal	83.7	82.4		
RBC, High	11.7	14.1		
Neutrophils, Low	18.3	15.6		
Neutrophils, Normal	80.9	83.6		
Neutrophils, High	0.8	0.8		
Lymphocytes, Low	1.9	0.4		
Lymphocytes, Normal	96.1	97.7		
Lymphocytes, High	1.9	2.0		
WBC, Low	5.4	3.1		
WBC, Normal	93.0	95.3		
WBC, High	1.6	1.6		
Haemoglobin, Low	39.7	35.5		
Haemoglobin, Normal	59.5	62.5		
Haemoglobin, High	0.8	2.0		
Platelets, Low	1.6	1.2		
Platelets, Normal	87.9	84.0		
Platelets, High	10.5	14.8		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, by age stratum

End point title	Percentage of subjects with haematological laboratory abnormalities, by age stratum[14]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 30

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	98	89	91
Units: Percentage of participants				
number (not applicable)				
RBC, Low	9.0	6.1	2.2	2.2
RBC, Normal	73.0	75.5	88.8	85.7
RBC, High	18.0	18.4	9.0	12.1
Neutrophils, Low	35.0	30.6	11.2	5.5
Neutrophils, Normal	65.0	69.4	87.6	92.3
Neutrophils, High	0	0	1.1	2.2
Lymphocytes, Low	0	0	0	0
Lymphocytes, Normal	98.0	96.9	97.8	100.0
Lymphocytes, High	2.0	3.1	2.2	0
WBC, Low	5.0	3.1	4.5	3.3
WBC, Normal	94.0	95.9	93.3	95.6
WBC, High	1.0	1.0	2.2	1.1
Haemoglobin, Low	37.0	67.3	61.8	64.8
Haemoglobin, Normal	62.0	1.0	0	0
Haemoglobin, High	1.0	0	0	0
Platelets, Low	0	0	0	0
Platelets, Normal	82.0	82.7	93.3	85.7
Platelets, High	18.0	17.3	6.7	14.3

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	67		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	1.5	1.5		
RBC, Normal	92.6	88.1		
RBC, High	5.9	10.4		
Neutrophils, Low	2.9	7.5		
Neutrophils, Normal	95.6	92.5		
Neutrophils, High	1.5	0		
Lymphocytes, Low	7.4	1.5		
Lymphocytes, Normal	91.2	95.5		
Lymphocytes, High	1.5	3.0		
WBC, Low	7.4	3.0		
WBC, Normal	91.2	94.0		
WBC, High	1.5	3.0		
Haemoglobin, Low	45.6	41.8		
Haemoglobin, Normal	52.9	52.2		
Haemoglobin, High	1.5	6.0		
Platelets, Low	5.9	4.5		
Platelets, Normal	89.7	83.6		

Platelets, High	4.4	11.9		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, overall

End point title	Percentage of subjects with haematological laboratory abnormalities, overall[15]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	257	254		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	7.8	6.7		
RBC, Normal	80.5	81.5		
RBC, High	11.7	11.8		
Neutrophils, Low	21.0	17.7		
Neutrophils, Normal	79.0	81.1		
Neutrophils, High	0	1.2		
Lymphocytes, Low	0.4	0		
Lymphocytes, Normal	97.7	97.6		
Lymphocytes, High	1.9	2.4		
WBC, Low	7.4	3.5		
WBC, Normal	92.2	93.7		
WBC, High	0.4	2.8		
Haemoglobin, Low	38.1	34.3		
Haemoglobin, Normal	61.9	65.7		
Haemoglobin, High	0	0		
Platelets, Low	0.8	0		
Platelets, Normal	88.7	85.8		
Platelets, High	10.5	14.2		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, by age stratum

End point title	Percentage of subjects with haematological laboratory abnormalities, by age stratum[16]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	96	89	91
Units: Percentage of participants				
number (not applicable)				
RBC, Low	16.0	15.6	2.2	1.1
RBC, Normal	78.0	76.0	78.7	78.0
RBC, High	6.0	8.3	19.1	20.9
Neutrophils, Low	38.0	28.1	7.9	12.1
Neutrophils, Normal	62.0	70.8	92.1	85.7
Neutrophils, High	0	1.0	0	2.2
Lymphocytes, Low	0	0	0	0
Lymphocytes, Normal	96.0	96.9	100.0	97.8
Lymphocytes, High	4.0	3.1	0	2.2
WBC, Low	6.0	4.2	3.4	2.2
WBC, Normal	93.0	92.7	96.6	94.5
WBC, High	1.0	3.1	0	3.3
Haemoglobin, Low	51.0	43.8	21.3	22.0
Haemoglobin, Normal	49.0	56.3	78.7	78.0
Haemoglobin, High	0	0	0	0
Platelets, Low	0	0	0	0
Platelets, Normal	89.0	87.5	87.6	85.7
Platelets, High	11.0	12.5	12.4	14.3

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	67		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	2.9	1.5		
RBC, Normal	86.8	94.0		
RBC, High	10.3	4.5		
Neutrophils, Low	13.2	10.4		
Neutrophils, Normal	86.8	89.6		
Neutrophils, High	0	0		
Lymphocytes, Low	1.5	0		
Lymphocytes, Normal	97.1	98.5		
Lymphocytes, High	1.5	1.5		
WBC, Low	14.7	4.5		
WBC, Normal	85.3	94.0		
WBC, High	0	1.5		
Haemoglobin, Low	41.2	37.3		
Haemoglobin, Normal	58.8	62.7		
Haemoglobin, High	0	0		
Platelets, Low	2.9	0		
Platelets, Normal	89.7	83.6		
Platelets, High	7.4	16.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, overall

End point title	Percentage of subjects with haematological laboratory abnormalities, overall[17]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6 + 6 Days

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	250		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	7.5	5.6		
RBC, Normal	84.6	83.6		
RBC, High	7.9	10.8		
Neutrophils, Low	20.9	28.8		
Neutrophils, Normal	78.7	71.2		
Neutrophils, High	0.4	0		
Lymphocytes, Low	0	0		
Lymphocytes, Normal	99.2	98.0		
Lymphocytes, High	0.8	2.0		
WBC, Low	4.3	7.6		
WBC, Normal	94.5	90.8		
WBC, High	1.2	1.6		
Haemoglobin, Low	38.7	41.6		
Haemoglobin, Normal	60.9	58.4		
Haemoglobin, High	0.4	0		
Platelets, Low	0.4	1.2		
Platelets, Normal	87.4	81.6		
Platelets, High	12.3	17.2		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, by age stratum

End point title	Percentage of subjects with haematological laboratory abnormalities, by age stratum[18]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6 + 6 Days

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	98	93	89	90
Units: Percentage of participants				
number (not applicable)				
RBC, Low	18.4	14.0	0	1.1
RBC, Normal	77.6	78.5	87.6	81.1
RBC, High	4.1	7.5	12.4	17.8
Neutrophils, Low	44.9	48.9	5.6	18.9
Neutrophils, Normal	55.1	51.6	93.3	81.1
Neutrophils, High	0	0	1.1	0
Lymphocytes, Low	0	0	0	0
Lymphocytes, Normal	98.0	96.8	100.0	97.8
Lymphocytes, High	2.0	3.2	0	2.2
WBC, Low	5.1	6.5	1.1	6.7
WBC, Normal	91.8	91.4	98.9	91.1
WBC, High	3.1	2.2	0	2.2
Haemoglobin, Low	56.1	51.6	19.1	27.8
Haemoglobin, Normal	43.9	48.4	80.9	72.2
Haemoglobin, High	0	0	0	0
Platelets, Low	0	0	0	0
Platelets, Normal	88.8	81.7	85.4	80.0
Platelets, High	11.2	18.3	14.6	20.0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	67		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	1.5	0		
RBC, Normal	90.9	94.0		
RBC, High	7.6	6.0		
Neutrophils, Low	6.1	14.9		
Neutrophils, Normal	93.9	85.1		
Neutrophils, High	0	0		
Lymphocytes, Low	0	0		
Lymphocytes, Normal	100.0	100.0		
Lymphocytes, High	0	0		
WBC, Low	7.6	10.4		
WBC, Normal	92.4	89.6		
WBC, High	0	0		
Haemoglobin, Low	39.4	46.3		
Haemoglobin, Normal	59.1	53.7		
Haemoglobin, High	1.5	0		
Platelets, Low	1.5	4.5		
Platelets, Normal	87.9	83.6		

Platelets, High	10.6	11.9		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, overall

End point title	Percentage of subjects with haematological laboratory abnormalities, overall[19]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6 + 30 Days

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	254	250		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	4.7	4.4		
RBC, Normal	81.9	83.6		
RBC, High	13.4	12.0		
Neutrophils, Low	24.4	25.6		
Neutrophils, Normal	75.6	73.2		
Neutrophils, High	0	1.2		
Lymphocytes, Low	0.8	0.8		
Lymphocytes, Normal	98.0	98.0		
Lymphocytes, High	1.2	1.2		
WBC, Low	5.5	6.4		
WBC, Normal	93.7	92.8		
WBC, High	0.8	0.8		
Haemoglobin, Low	35.0	37.6		
Haemoglobin, Normal	65.0	62.0		
Haemoglobin, High	0	0.4		
Platelets, Low	0.4	1.6		
Platelets, Normal	86.2	85.2		
Platelets, High	13.4	13.2		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, by age stratum

End point title	Percentage of subjects with haematological laboratory abnormalities, by age stratum[20]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6 + 30 Days

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	98	93	89	90
Units: Percentage of participants				
number (not applicable)				
RBC, Low	9.2	11.8	2.2	0
RBC, Normal	76.5	74.2	82.0	86.7
RBC, High	14.3	14.0	15.7	13.3
Neutrophils, Low	52.0	57.0	10.1	8.9
Neutrophils, Normal	48.0	43.0	89.9	87.8
Neutrophils, High	0	0	0	3.3
Lymphocytes, Low	0	0	1.1	1.1
Lymphocytes, Normal	98.0	97.8	98.9	98.9
Lymphocytes, High	2.0	2.2	0	0
WBC, Low	7.1	7.5	3.4	6.7
WBC, Normal	90.8	92.5	96.6	92.2
WBC, High	2.0	0	0	1.1
Haemoglobin, Low	44.9	37.6	24.7	28.9
Haemoglobin, Normal	55.1	62.4	75.3	71.1
Haemoglobin, High	0	0	0	0
Platelets, Low	0	2.2	1.1	2.2
Platelets, Normal	84.7	86.0	86.5	87.8
Platelets, High	15.3	11.8	12.4	10.0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	67	67		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	1.5	0		
RBC, Normal	89.6	92.5		
RBC, High	9.0	7.5		
Neutrophils, Low	3.0	4.5		
Neutrophils, Normal	97.0	95.5		
Neutrophils, High	0	0		
Lymphocytes, Low	1.5	1.5		
Lymphocytes, Normal	97.0	97.0		
Lymphocytes, High	1.5	1.5		
WBC, Low	6.0	4.5		
WBC, Normal	94.0	94.0		
WBC, High	0	1.5		
Haemoglobin, Low	34.3	49.3		
Haemoglobin, Normal	65.7	49.3		
Haemoglobin, High	0	1.5		
Platelets, Low	0	0		
Platelets, Normal	88.1	80.6		
Platelets, High	11.9	19.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, overall

End point title	Percentage of subjects with haematological laboratory abnormalities, overall[21]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 12

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	254		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	6.3	10.2		
RBC, Normal	83.0	81.1		
RBC, High	10.7	8.7		
Neutrophils, Low	22.1	18.5		
Neutrophils, Normal	77.9	81.5		
Neutrophils, High	0	0		
Lymphocytes, Low	0.4	0.8		
Lymphocytes, Normal	99.2	97.6		
Lymphocytes, High	0.4	1.6		
WBC, Low	6.3	4.7		
WBC, Normal	92.9	93.3		
WBC, High	0.8	2.0		
Haemoglobin, Low	42.7	46.1		
Haemoglobin, Normal	56.9	53.9		
Haemoglobin, High	0.4	0		
Platelets, Low	0.8	1.2		
Platelets, Normal	87.0	83.9		
Platelets, High	12.3	15.0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with haematological laboratory abnormalities, by age stratum

End point title	Percentage of subjects with haematological laboratory abnormalities, by age stratum[22]

End point description:

Haematological parameters assessed included: complete blood count (red blood cells [RBC], neutrophils, lymphocytes, white blood cells [WBC], haemoglobin, as well as differential count and platelet count for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 12

Notes:

[22] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	97	88	90
Units: Percentage of participants				
number (not applicable)				
RBC, Low	13.0	23.7	3.4	0
RBC, Normal	74.0	64.9	86.4	88.9
RBC, High	13.0	11.3	10.2	11.1
Neutrophils, Low	47.0	40.2	2.3	6.7
Neutrophils, Normal	53.0	59.8	97.7	93.3
Neutrophils, High	0	0	0	0
Lymphocytes, Low	1.0	0	0	1.1
Lymphocytes, Normal	98.0	96.6	100.0	97.8
Lymphocytes, High	1.0	3.1	0	1.1
WBC, Low	5.0	8.2	3.4	2.2
WBC, Normal	93.0	86.6	96.6	97.8
WBC, High	2.0	5.2	0	0
Haemoglobin, Low	50.0	53.6	31.8	32.2
Haemoglobin, Normal	50.0	46.4	68.2	67.8
Haemoglobin, High	0	0	0	0
Platelets, Low	1.0	2.1	0	0
Platelets, Normal	82.0	80.4	86.4	85.6
Platelets, High	17.0	17.5	13.6	14.4

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	101	99		
Units: Percentage of participants				
number (not applicable)				
RBC, Low	0	4.5		
RBC, Normal	92.3	94.0		
RBC, High	7.7	1.5		
Neutrophils, Low	10.8	3.0		
Neutrophils, Normal	89.2	97.0		
Neutrophils, High	0	0		
Lymphocytes, Low	0	1.5		
Lymphocytes, Normal	100.0	98.5		
Lymphocytes, High	0	0		
WBC, Low	12.3	3.0		
WBC, Normal	87.7	97.0		
WBC, High	0	0		
Haemoglobin, Low	46.2	53.7		
Haemoglobin, Normal	52.3	46.3		
Haemoglobin, High	1.5	0		
Platelets, Low	1.5	1.5		
Platelets, Normal	96.4	86.6		

Platelets, High	3.1	11.9		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, overall

End point title	Percentage of subjects with biochemical laboratory abnormalities, overall[23]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Screening.

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	257	258		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	24.1	29.1		
ALT, Normal	75.1	70.5		
ALT, High	0.8	0.4		
CRE, Low	3.5	2.3		
CRE, Normal	89.9	92.2		
CRE, High	6.6	5.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, by age stratum

End point title	Percentage of subjects with biochemical laboratory abnormalities, by age stratum[24]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Screening

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	89	91
Units: Percentage of participants				
number (not applicable)				
ALT, Low	24.0	35.0	27.0	27.5
ALT, Normal	76.0	65.0	70.8	71.4
ALT, High	0	0	2.2	1.1
CRE, Low	2.0	3.0	0	0
CRE, Normal	83.0	84.0	97.8	98.9
CRE, High	15.0	13.0	2.2	1.1

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	67		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	20.6	22.4		
ALT, Normal	79.4	77.6		
ALT, High	0	0		
CRE, Low	10.3	4.5		
CRE, Normal	89.7	95.5		
CRE, High	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, overall

End point title	Percentage of subjects with biochemical laboratory abnormalities, overall[25]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 3

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	257	257		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	26.1	29.6		
ALT, Normal	73.5	69.3		
ALT, High	0.4	1.2		
CRE, Low	1.2	1.6		
CRE, Normal	93.4	90.7		
CRE, High	5.4	7.8		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, by age stratum

End point title	Percentage of subjects with biochemical laboratory abnormalities, by age stratum[26]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 3

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	89	91
Units: Percentage of participants				
number (not applicable)				
ALT, Low	31.0	43.0	28.1	23.1
ALT, Normal	69.0	57.0	71.9	74.7
ALT, High	0	0	0	2.2
CRE, Low	1.0	3.0	0	0
CRE, Normal	85.0	78.0	100.0	98.9
CRE, High	14.0	19.0	0	1.1

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	66		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	16.2	18.2		
ALT, Normal	82.4	80.3		
ALT, High	1.5	1.5		
CRE, Low	2.9	1.5		
CRE, Normal	97.1	98.5		
CRE, High	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, overall

End point title	Percentage of subjects with biochemical laboratory abnormalities, overall[27]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 6

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	256	256		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	27.7	29.3		
ALT, Normal	71.9	69.9		
ALT, High	0.4	0.8		
CRE, Low	2.7	2.0		
CRE, Normal	89.5	93.4		
CRE, High	7.8	4.7		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, by age stratum

End point title	Percentage of subjects with biochemical laboratory abnormalities, by age stratum[28]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 6

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	99	98	89	91
Units: Percentage of particcipants				
number (not applicable)				
ALT, Low	31.3	39.8	25.8	24.2
ALT, Normal	68.7	60.2	74.2	74.7
ALT, High	0	0	0	1.1
CRE, Low	2.0	2.0	0	0
CRE, Normal	77.8	85.7	100.0	100.0
CRE, High	20.2	12.2	0	0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	67		
Units: Percentage of particcipants				
number (not applicable)				
ALT, Low	25.0	20.9		
ALT, Normal	73.5	77.6		
ALT, High	1.5	1.5		
CRE, Low	7.4	4.5		

CRE, Normal	92.6	95.5		
CRE, High	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, overall

End point title	Percentage of subjects with biochemical laboratory abnormalities, overall[29]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 30

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

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	257	256		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	29.6	28.9		
ALT, Normal	70.0	71.1		
ALT, High	0.4	0		
CRE, Low	2.3	2.0		
CRE, Normal	90.3	89.5		
CRE, High	7.4	8.6		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, by age stratum

End point title	Percentage of subjects with biochemical laboratory abnormalities, by age stratum[30]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Day 30

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	98	89	91
Units: Percentage of participants				
number (not applicable)				
ALT, Low	30.0	40.8	33.7	29.7
ALT, Normal	70.0	59.2	65.2	70.3
ALT, High	0	0	1.1	0
CRE, Low	1.0	3.1	0	1.1
CRE, Normal	82.0	75.5	100.0	98.9
CRE, High	17.0	21.4	0	0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	67		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	23.5	10.4		
ALT, Normal	76.5	89.6		
ALT, High	0	0		
CRE, Low	7.4	1.5		
CRE, Normal	89.7	97.0		
CRE, High	2.9	1.5		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, overall

End point title	Percentage of subjects with biochemical laboratory abnormalities, overall[31]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6

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

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	257	254		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	20.2	15.4		
ALT, Normal	79.4	84.3		
ALT, High	0.4	0.4		
CRE, Low	14.0	13.0		
CRE, Normal	84.4	86.6		
CRE, High	1.6	0.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, by age stratum

End point title	Percentage of subjects with biochemical laboratory abnormalities, by age stratum[32]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	96	89	91
Units: Percentage of participants				
number (not applicable)				
ALT, Low	18.0	20.8	12.4	8.8
ALT, Normal	82.0	78.1	86.5	91.2
ALT, High	0	1.0	1.1	0
CRE, Low	27.0	22.9	0	0
CRE, Normal	70.0	76.0	100.0	100.0
CRE, High	3.0	1.0	0	0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	68	67		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	33.8	16.4		
ALT, Normal	66.2	83.6		
ALT, High	0	0		
CRE, Low	13.2	16.4		
CRE, Normal	85.3	83.6		
CRE, High	1.5	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, overall

End point title	Percentage of subjects with biochemical laboratory abnormalities, overall[33]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6 + 6 Days

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

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	250		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	19.8	22.4		
ALT, Normal	79.1	77.6		
ALT, High	1.2	0		
CRE, Low	13.8	13.2		
CRE, Normal	85.4	86.4		
CRE, High	0.8	0.4		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, by age stratum

End point title	Percentage of subjects with biochemical laboratory abnormalities, by age stratum[34]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6 + 6 Days

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

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	98	93	89	90
Units: Percentage of participants				
number (not applicable)				
ALT, Low	17.3	28.0	14.6	17.8
ALT, Normal	81.6	72.0	83.1	82.2
ALT, High	1.0	0	2.2	0
CRE, Low	26.5	29.0	2.2	0
CRE, Normal	71.4	71.0	97.8	98.9
CRE, High	2.0	0	0	1.1

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	66	67		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	30.3	20.9		
ALT, Normal	69.7	79.1		
ALT, High	0	0		
CRE, Low	10.6	9.0		

CRE, Normal	89.4	91.0		
CRE, High	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, overall

End point title	Percentage of subjects with biochemical laboratory abnormalities, overall[35]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6 + 30 Days

Notes:

[35] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	254	250		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	15.7	17.2		
ALT, Normal	82.3	81.2		
ALT, High	2.0	1.6		
CRE, Low	15.4	15.2		
CRE, Normal	83.1	83.6		
CRE, High	1.6	1.2		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, by age stratum

End point title	Percentage of subjects with biochemical laboratory abnormalities, by age stratum[36]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 6 + 30 Days

Notes:

[36] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	98	93	89	90
Units: Percentage of participants				
number (not applicable)				
ALT, Low	14.3	17.2	10.1	13.3
ALT, Normal	82.7	82.8	87.6	83.3
ALT, High	3.1	0	2.2	3.3
CRE, Low	27.6	33.3	2.2	0
CRE, Normal	71.4	66.7	95.5	96.7
CRE, High	1.0	0	2.2	3.3

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	67	67		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	25.4	22.4		
ALT, Normal	74.6	76.1		
ALT, High	0	1.5		
CRE, Low	0	1.5		
CRE, Normal	14.9	10.4		
CRE, High	83.6	89.6		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, overall

End point title	Percentage of subjects with biochemical laboratory abnormalities, overall[37]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for all subjects, in both groups. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 12.

Notes:

[37] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	253	254		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	32.4	26.4		
ALT, Normal	66.8	72.0		
ALT, High	0.8	1.6		
CRE, Low	15.4	15.0		
CRE, Normal	77.1	79.5		
CRE, High	7.5	5.5		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of subjects with biochemical laboratory abnormalities, by age stratum

End point title	Percentage of subjects with biochemical laboratory abnormalities, by age stratum[38]

End point description:

Biochemical parameters assessed included: alanine aminotransferase [ALT], creatinine [CRE] for subjects aged 1-5 years, 6-12 years and 13-17 years. Reference range indicators used were: high, low, normal.

End point type	Primary

End point timeframe:

At Month 12

Notes:

[38] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	97	88	90
Units: Percentage of participants				
number (not applicable)				
ALT, Low	26.0	27.8	39.8	25.6
ALT, Normal	73.0	71.1	59.1	74.4
ALT, High	1.0	1.0	1.1	0
CRE, Low	21.0	18.6	6.8	7.8
CRE, Normal	73.0	77.3	79.5	83.3
CRE, High	6.0	4.1	13.6	8.9

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	65	67		
Units: Percentage of participants				
number (not applicable)				
ALT, Low	32.3	25.4		
ALT, Normal	67.7	70.1		
ALT, High	0	4.5		
CRE, Low	18.5	19.4		
CRE, Normal	80.0	77.6		
CRE, High	1.5	3.0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with adverse events of specific interest (AESI), overall

End point title	Number of subjects with adverse events of specific interest (AESI), overall[39]

End point description:

AESI included clinical symptoms of thrombocytopenia for all subjects, in both groups.

End point type	Primary

End point timeframe:

During the 7 day follow-up period after vaccination at Day 0 (i.e., Day 0 up to Day 6)

Notes:

[39] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with adverse events of specific interest (AESI), by age stratum

End point title	Number of subjects with adverse events of specific interest

	(AESI), by age stratum[40]

End point description:

AESI included clinical symptoms of thrombocytopenia for subjects aged 1-5 years, 6-12 years and 13-17 years.

End point type	Primary

End point timeframe:

During the 7 day follow-up period after vaccination at Day 0 (i.e. Day 0 up to Day 6)

Notes:

[40] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	99	100	100	99
Units: Participants	0	0	0	0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	101	101		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events, overall

End point title	Number of subjects with serious adverse events, overall[41]

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity. SAEs, for this endpoint, were assessed in all subjects, in both groups.

End point type	Primary

End point timeframe:

During the entire study period: From Day 0 to Month 12

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	300	300		
Units: Participants	2	2		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events, by age stratum

End point title	Number of subjects with serious adverse events, by age stratum[42]

End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity. SAEs, for this endpoint, were assessed in subjects aged 1-5 years, 6-12 years and 13-17 years.

End point type	Primary

End point timeframe:

During the entire study period: From Day 0 to Month 12

Notes:

[42] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The scope of this primary endpoint was descriptive, no statistical analyses were conducted.

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	99	100	100	99
Units: Participants	0	0	1	1

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	101	101		
Units: Participants	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-glycoprotein (anti-GP) Ebola Virus Zaire (EBOV) antibody titers, overall

End point title	Anti-glycoprotein (anti-GP) Ebola Virus Zaire (EBOV) antibody titers, overall

End point description:

Anti-GP EBOV antibodies were expressed as Geometric Mean Titers (GMTs), as measured by the Enzyme-Linked Immunosorbent Assay (ELISA) and assessed in all subjects, in both groups.

End point type	Secondary

End point timeframe:

At Day 0, Day 30, Month 6, Month 6 + 30 Days and Month 12.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	295	294		
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-GP EBOV, Day 0	24.755 (22.673 to 27.029)	24.587 (22.612 to 26.735)		
Anti-GP EBOV, Day 30	1739.756 (1562.966 to 1936.543)	24.372 (22.236 to 26.714)		
Anti-GP EBOV, Month 6	1017.712 (925.011 to 1119.702)	23.343 (21.616 to 25.208)		
Anti-GP EBOV, Month 6 + Day 30	970.870 (883.886 to 1066.414)	1513.928 (1370.915 to 1671.859)		
Anti-GP EBOV, Month 12	909.092 (813.891 to 1015.429)	889.641 (800.009 to 989.315)		

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-GP EBOV antibody titers, by age stratum

End point title	Anti-GP EBOV antibody titers, by age stratum

End point description:

Anti-GP EBOV antibodies were expressed as Geometric Mean Titers (GMTs), as measured by the Enzyme-Linked Immunosorbent Assay (ELISA) and assessed in subjects aged 1-5 years, 6-12 years and 13-17 years.

End point type	Secondary

End point timeframe:

At Day 0, Day 30, Month 6, Month 6 + 30 Days and Month 12

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	96	98
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-GP EBOV, Day 0	29.526 (24.175 to 36.062)	31.545 (26.543 to 37.489)	22.764 (20.195 to 25.661)	21.241 (18.973 to 23.780)
Anti-GP EBOV, Day 30	1564.283 (1339.748 to 1826.449)	29.565 (24.794 to 35.254)	1394.540 (1174.847 to 1655.316)	21.879 (19.098 to 25.065)
Anti-GP EBOV, Month 6	705.913 (619.567 to 804.292)	23.328 (20.814 to 26.146)	1030.880 (887.724 to 1197.121)	21.834 (19.476 to 24.478)
Anti-GP EBOV, Month 6 + 30 Days	722.550 (638.466 to 817.708)	1150.199 (971.093 to 1362.339)	885.295 (766.161 to 1022.954)	1399.458 (1188.609 to 1647.710)
Anti-GP EBOV, Month 12	715.890 (619.208 to 827.668)	583.371 (486.760 to 699.158)	751.765 (645.194 to 875.939)	883.668 (759.207 to 1028.533)

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	99	96		
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-GP EBOV, Day 0	22.473 (19.966 to 25.295)	22.021 (19.281 to 25.151)		
Anti-GP EBOV, Day 30	2405.635 (1942.446 to 2979.274)	22.300 (18.991 to 26.186)		
Anti-GP EBOV, Month 6	1482.304 (1231.572 to 1784.081)	25.141 (21.161 to 29.871)		
Anti-GP EBOV, Month 6 + 30 Days	1439.460 (1193.726 to 1735.780)	2190.763 (1862.359 to 2577.076)		
Anti-GP EBOV, Month 12	1424.270 (1118.513 to 1813.608)	1412.293 (1179.201 to 1691.459)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of seronegative/seropositive subjects for anti-GP EBOV antibodies, overall

End point title	Percentage of seronegative/seropositive subjects for anti-GP

	EBOV antibodies, overall

End point description:

A seronegative subject is a subject whose titer is below the cut-off value. A seropositive subject is a subject whose titer is greater than or equal to the cut-off value. The analysis, for this endpoint, was performed on all subjects, in both groups.

End point type	Secondary

End point timeframe:

At Day 0, Day 30, Month 6 and Month 6 + 30 Days.

End point values	GSK3390107A +Nimenrix Group	Nimenrix+GSK 3390107A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	295	294		
Units: Percentage of participants				
number (not applicable)				
Anti-GP EBOV, Day 0, S-	82.7	82.3		
Anti-GP EBOV, Day 0, S+	17.3	17.7		
Anti-GP EBOV, Day 30, S-	0.7	83.8		
Anti-GP EBOV, Day 30, S+	99.3	16.2		
Anti-GP EBOV, Month 6, S-	0.0	84.0		
Anti-GP EBOV, Month 6, S+	100.0	16.0		
Anti-GP EBOV, Month 6 + 30 Days, S-	0.0	0.0		
Anti-GP EBOV, Month 6 + 30 Days, S+	100.0	100.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of seronegative/seropositive subjects for anti-GP EBOV antibodies, by age stratum

End point title	Percentage of seronegative/seropositive subjects for anti-GP EBOV antibodies, by age stratum

End point description:

A seronegative subject is a subject whose titer is below the cut-off value. A seropositive subject is a subject whose titer is greater than or equal to the cut-off value. The analysis, for this endpoint, was performed on subjects aged 1-5 years, 6-12 years and 13-17 years.

End point type	Secondary

End point timeframe:

At Day 0, Day 30, Month 6 and Month 6 + 30 Days

End point values	GSK3390107A +Nimenrix 13-17YOA Group	Nimenrix+GSK 3390107A 13-17YOA Group	GSK3390107A +Nimenrix 6-12YOA Group	Nimenrix+GSK 3390107A 6-12YOA Group
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	100	100	96	98
Units: Percentage of participants				
number (not applicable)				
Anti-GP EBOV, Day 0, S-	77.0	67.0	85.4	90.8
Anti-GP EBOV, Day 0, S+	23.0	33.0	14.6	9.2
Anti-GP EBOV, Day 30, S-	0	70.4	0	90.8
Anti-GP EBOV, Day 30, S+	100.0	29.6	100.0	9.2
Anti-GP EBOV, Month 6, S-	0	80.0	0	88.8
Anti-GP EBOV, Month 6, S+	100.0	20.0	100.0	11.2
Anti-GP EBOV, Month 6 + 30 Days, S-	0	0	0	0
Anti-GP EBOV, Month 6 + 30 Days, S+	100.0	100.0	100.0	100.0

End point values	GSK3390107A +Nimenrix 1-5YOA Group	Nimenrix+GSK 3390107A 1-5YOA Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	99	96		
Units: Percentage of participants				
number (not applicable)				
Anti-GP EBOV, Day 0, S-	85.9	89.6		
Anti-GP EBOV, Day 0, S+	14.1	10.4		
Anti-GP EBOV, Day 30, S-	2.0	90.4		
Anti-GP EBOV, Day 30, S+	98.0	9.6		
Anti-GP EBOV, Month 6, S-	0	83.1		
Anti-GP EBOV, Month 6, S+	100.0	16.9		
Anti-GP EBOV, Month 6 + 30 Days, S-	0	0		
Anti-GP EBOV, Month 6 + 30 Days, S+	100.0	100.0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: during the 7-day (Days 0-6) post-vaccination period; Unsolicited AEs: during the 30-day (Days 0-29) post-vaccination period; SAEs: from Screening up to study end at Month 12.

Adverse event reporting additional description:

From Screening to Day 0, only those SAEs that were considered related to study participation or to concurrent use of GlaxoSmithKline (GSK) medication/ vaccine needed to be recorded.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	GSK3390107A+Nimenrix Group

Reporting group description:

Subjects in the GSK3390107A+Nimenrix Group received the investigational GSK3390107A vaccine at the Day 0 visit and Nimenrix at the Month 6 visit, intramuscularly into the deltoid region, or thigh region for smaller children.

Reporting group title	Nimenrix+GSK3390107A Group

Reporting group description:

Subjects in the Nimenrix+GSK3390107A Group received Nimenrix at the Day 0 visit and the investigational GSK3390107A vaccine at the Month 6 visit, intramuscularly into the deltoid region, or thigh region for smaller children.

Serious adverse events	GSK3390107A+Nimenrix Group	Nimenrix+GSK3390107A Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 300 (0.67%)	3 / 300 (1.00%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events	0	0	
General disorders and administration site conditions			
DEATH			
subjects affected / exposed	1 / 300 (0.33%)	0 / 300 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
APPENDICITIS PERFORATED			
subjects affected / exposed	0 / 300 (0.00%)	1 / 300 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATITIS B			

subjects affected / exposed	0 / 300 (0.00%)	1 / 300 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
HEPATITIS D			
subjects affected / exposed	0 / 300 (0.00%)	1 / 300 (0.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
MALARIA			
subjects affected / exposed	1 / 300 (0.33%)	0 / 300 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	GSK3390107A+Nimenrix Group	Nimenrix+GSK3390107A Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	194 / 300 (64.67%)	89 / 300 (29.67%)	
Nervous system disorders			
HEADACHE			
subjects affected / exposed	62 / 300 (20.67%)	17 / 300 (5.67%)	
occurrences (all)	72	19	
SOMNOLENCE			
subjects affected / exposed	26 / 300 (8.67%)	2 / 300 (0.67%)	
occurrences (all)	37	2	
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	33 / 300 (11.00%)	6 / 300 (2.00%)	
occurrences (all)	37	8	
PAIN			
subjects affected / exposed	127 / 300 (42.33%)	60 / 300 (20.00%)	
occurrences (all)	189	82	
PYREXIA			
subjects affected / exposed	95 / 300 (31.67%)	28 / 300 (9.33%)	
occurrences (all)	112	37	
Gastrointestinal disorders			

GASTROINTESTINAL DISORDER subjects affected / exposed occurrences (all)	16 / 300 (5.33%) 22	6 / 300 (2.00%) 8	
Metabolism and nutrition disorders DECREASED APPETITE subjects affected / exposed occurrences (all)	24 / 300 (8.00%) 32	4 / 300 (1.33%) 6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 December 2014	The rationale or background for changes was the following: • For robustness of safety monitoring, the GSK Biologicals' internal safety review committee (iSRC) was replaced by an independent data monitoring committee (IDMC). • Indicate that safety and reactogenicity data will be collected in 100 adults after 1 week of follow-up (study EBOLA Z CHAD3-005) before commencing the current study. • Indicate that safety and reactogenicity data obtained in the context of the age de-escalation process may lead to the selection of a lower ChAd3-EBO-Z vaccine dose in the younger age groups. • Clarify that informed assent will be asked from all subjects in the oldest age stratum (13 to 17 years of age) and from younger subjects as per local requirements. • Define grading scales for local injection site redness/ swelling per age stratum. • Clarify that analysis of safety will be done on the total vaccinated cohort (TVC) and that no according-to-protocol (ATP) cohort for safety will be defined. • Include information on the anti-GP ELISA testing (laboratory, test description).
06 May 2015	In the on-going Phase 1 studies with the investigational ChAd3-EBO-Z vaccine in the United States (US), United Kingdom (UK), Switzerland and Mali, transient decreases in thrombocyte counts were observed. These decreases occurred mostly on Day 1 after vaccination and generally returned to baseline by Day 7. Although most of these decreases remained within the normal range, the as per protocol criteria for thrombocytopenia (thrombocyte count of < 150x103/µL) were met for 2.6% (7 out of 270) of the vaccinated subjects. None of the decreases in thrombocyte counts or the cases of thrombocytopenia were clinically significant, i.e., no clinical signs or symptoms suggestive of increased tendency to bleed were reported in any of the subjects. Please refer to the Investigator's Brochure (IB) for more information. In the current study, a more vulnerable population (children) will be enrolled and the acceptable limit for the thrombocyte count for study eligibility (thrombocyte count of 100x103/µL is acceptable) will be lower as compared to the Phase 1 studies. In addition, in order to ensure enhanced vigilance from the Investigators, clinical bleeding events (according to the Standardised Medical Dictionary for Regulatory Activities [MedDRA] Query clinical haemorrhage) within 7 days after vaccination at Day 0 will be recorded and reported as adverse events (AEs) of specific interest (clinical symptoms of thrombocytopenia).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported