

**Clinical trial results:**

A Phase 1/2, randomized, observer-blind, controlled, multi-center study to evaluate safety, reactogenicity and immunogenicity of GSK Biologicals' respiratory syncytial virus (RSV) investigational vaccine based on the RSV viral proteins F, N and M2-1 encoded by chimpanzee-derived adenovector (ChAd155-RSV) (GSK3389245A), when administered intramuscularly as a single dose or as two doses according to a 0, 1-month schedule, to infants aged 6 and 7 months

Summary

EudraCT number	2018-000431-27
Trial protocol	FI BE ES GB PL IT
Global end of trial date	16 November 2021

Results information

Result version number	v1 (current)
This version publication date	29 May 2022
First version publication date	29 May 2022

Trial information**Trial identification**

Sponsor protocol code	204894
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 044 8664357343, 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	28 February 2022
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 January 2020
Global end of trial reached?	Yes
Global end of trial date	16 November 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and reactogenicity of the RSV investigational vaccine when administered intramuscular (IM) as one (1.5×10^{10} vp) dose or as two (5×10^{10} vp) doses according to a 0, 1-month schedule, up to 60 days after Dose 1 (i.e., Day 61) in infants aged 6 and 7 months.

Protection of trial subjects:

Subjects remained under observation for at least 60 minutes after first vaccination with study vaccine and were supervised for at least 30 minutes during subsequent vaccinations for the full course of the ChAd155-RSV (GSK3389245A) vaccine, with appropriate medical treatment readily available. Vaccines were always administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 April 2019
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	Canada: 12
Country: Number of subjects enrolled	Colombia: 9
Country: Number of subjects enrolled	Brazil: 16
Country: Number of subjects enrolled	Finland: 11
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	Panama: 56
Country: Number of subjects enrolled	Poland: 20
Country: Number of subjects enrolled	Spain: 45
Country: Number of subjects enrolled	Thailand: 3
Country: Number of subjects enrolled	Turkey: 17
Country: Number of subjects enrolled	United Kingdom: 2
Country: Number of subjects enrolled	United States: 3
Worldwide total number of subjects	201
EEA total number of subjects	78

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)	201
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

All 201 subjects enrolled in the study received a study vaccination and were included in the Exposed Set.

Period 1

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

Blinding implementation details:

The study was conducted in an observer-blind manner.

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV1D Group

Arm description:

Subjects received the interventions as follows:

-Either 1 dose of experimental RSV (GSK3389245A) lower dose formulation at Day 1, followed by 1 dose of Placebo at Day 31 and any one the following active comparators: 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 61 and at the end of RSV season 1) or 3 doses of GSK's multicomponent meningococcal B vaccine or Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine or GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 61, 121 and at the end of RSV season 1).

-Or 1 dose of experimental RSV (GSK3389245A) lower dose formulation at Day 1, followed by 1 dose of Placebo at Day 31.

Arm type	Experimental
Investigational medicinal product name	RSV (GSK3389245A) lower dose formulation vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

1 dose of RSV (GSK3389245A) lower dose formulation vaccine administered intramuscularly at Day 1.

Investigational medicinal product name	GSK's multicomponent meningococcal B vaccine
Investigational medicinal product code	
Other name	Bexsero
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of GSK's multicomponent meningococcal B vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 1, Day 61 and end of RSV season 1, depending on the vaccination schedule.

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

Dosage and administration details:

1 dose or 2 doses of Placebo administered intramuscularly at Day 31, or at Day 1 and Day 31, or at Day 1 and Day 61, or at Day 1 and Day 121, or at Day 31 and Day 121, depending on the vaccination schedule.

Investigational medicinal product name	Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine
Investigational medicinal product code	
Other name	Nimenrix
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 1, Day 61 and end of RSV season 1, depending on the vaccination schedule.

Investigational medicinal product name	GSK's meningococcal group A, C, W-135 and Y conjugate vaccine
Investigational medicinal product code	
Other name	Menveo
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine administered intramuscularly, at Day 61 and at the end of RSV season 1, or at Day 31 and end of RSV season 1, depending on the vaccination schedule.

Investigational medicinal product name	GSK's pneumococcal polysaccharide conjugate vaccine
Investigational medicinal product code	
Other name	Synflorix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of GSK's pneumococcal polysaccharide conjugate vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 31, Day 61 and end of RSV season 1, depending on the vaccination schedule.

Arm title	RSV2D Group
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Arm description:

Subjects received the interventions as follows:

-Either 2 doses of experimental RSV (GSK3389245A) higher dose formulation (administered at Day 1 and Day 31) and followed by any one the following active comparators: 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 61 and at the end of RSV season 1) or 3 doses of GSK's multicomponent meningococcal B vaccine or Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine or GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 61, 121 and at the end of RSV season 1).

-Or 2 doses of experimental RSV (GSK3389245A) higher dose formulation administered at Day 1 and Day 31.

Arm type	Experimental
Investigational medicinal product name	Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine
Investigational medicinal product code	
Other name	Nimenrix
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 1, Day 61 and end of RSV season 1, depending on the vaccination schedule.

Investigational medicinal product name	RSV (GSK3389245A) higher dose formulation vaccine
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
2 doses of RSV (GSK3389245A) higher dose formulation vaccine administered intramuscularly, at Day 1 and Day 31.	
Investigational medicinal product name	GSK's multicomponent meningococcal B vaccine
Investigational medicinal product code	
Other name	Bexsero
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
3 doses of GSK's multicomponent meningococcal B vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 1, Day 61 and end of RSV season 1, depending on the vaccination schedule.	
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
1 dose or 2 doses of Placebo administered intramuscularly at Day 31, or at Day 1 and Day 31, or at Day 1 and Day 61, or at Day 31 and Day 121, depending on the vaccination schedule.	
Investigational medicinal product name	GSK's meningococcal group A, C, W-135 and Y conjugate vaccine
Investigational medicinal product code	
Other name	Menveo
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine administered intramuscularly, at Day 61 and at the end of RSV season 1, or at Day 31 and end of RSV season 1, depending on the vaccination schedule.	
Investigational medicinal product name	GSK's pneumococcal polysaccharide conjugate vaccine
Investigational medicinal product code	
Other name	Synflorix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use
Dosage and administration details:	
3 doses of GSK's pneumococcal polysaccharide conjugate vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 31, Day 61 and end of RSV season 1, depending on the vaccination schedule.	
Arm title	Comparator_Placebo Group
Arm description:	
Subjects received either one of interventions schedules as follows:	
-3 doses of GSK's multicomponent meningococcal B vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121). -3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121).	
-3 doses of GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 31, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Day 1 and Day 121).	
-2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 31 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 1 and 61) .	
-2 doses of Placebo alone (administered at Days 1 and 31).	
Arm type	Active comparator

Investigational medicinal product name	GSK's multicomponent meningococcal B vaccine
Investigational medicinal product code	
Other name	Bexsero
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of GSK's multicomponent meningococcal B vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 1, Day 61 and end of RSV season 1, depending on the vaccination schedule.

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

Dosage and administration details:

1 dose or 2 doses of Placebo administered intramuscularly at Day 31, or at Day 1 and Day 31, or at Day 1 and Day 61, or at Day 31 and Day 121, depending on the vaccination schedule.

Investigational medicinal product name	Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine
Investigational medicinal product code	
Other name	Nimenrix
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 1, Day 61 and end of RSV season 1, depending on the vaccination schedule.

Investigational medicinal product name	GSK's meningococcal group A, C, W-135 and Y conjugate vaccine
Investigational medicinal product code	
Other name	Menveo
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine administered intramuscularly, at Day 61 and at the end of RSV season 1, or at Day 31 and end of RSV season 1, depending on the vaccination schedule.

Investigational medicinal product name	GSK's pneumococcal polysaccharide conjugate vaccine
Investigational medicinal product code	
Other name	Synflorix
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

3 doses of GSK's pneumococcal polysaccharide conjugate vaccine administered intramuscularly, at Day 61, Day 121 and at the end of RSV season 1, or at Day 31, Day 61 and end of RSV season 1, depending on the vaccination schedule.

Number of subjects in period 1	RSV1D Group	RSV2D Group	Comparator_Placebo Group
Started	65	71	65
Completed	61	71	60
Not completed	4	0	5
CONSENT WITHDRAWAL, NOT DUE TO AN AE AND/OR A SAE	2	-	1
NOT WILLING TO PARTICIPATE THIS VISIT	1	-	2
Adverse event, non-fatal	-	-	1
Not specified	-	-	1
Lost to follow-up	1	-	-

Baseline characteristics

Reporting groups

Reporting group title	RSV1D Group
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Reporting group description:

Subjects received the interventions as follows:

-Either 1 dose of experimental RSV (GSK3389245A) lower dose formulation at Day 1, followed by 1 dose of Placebo at Day 31 and any one the following active comparators: 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 61 and at the end of RSV season 1) or 3 doses of GSK's multicomponent meningococcal B vaccine or Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine or GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 61, 121 and at the end of RSV season 1).

-Or 1 dose of experimental RSV (GSK3389245A) lower dose formulation at Day 1, followed by 1 dose of Placebo at Day 31.

Reporting group title	RSV2D Group
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Reporting group description:

Subjects received the interventions as follows:

-Either 2 doses of experimental RSV (GSK3389245A) higher dose formulation (administered at Day 1 and Day 31) and followed by any one the following active comparators: 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 61 and at the end of RSV season 1) or 3 doses of GSK's multicomponent meningococcal B vaccine or Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine or GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 61, 121 and at the end of RSV season 1).

-Or 2 doses of experimental RSV (GSK3389245A) higher dose formulation administered at Day 1 and Day 31.

Reporting group title	Comparator_Placebo Group
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Reporting group description:

Subjects received either one of interventions schedules as follows:

-3 doses of GSK's multicomponent meningococcal B vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121). -3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121).

-3 doses of GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 31, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Day 1 and Day 121).

-2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 31 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 1 and 61) .

-2 doses of Placebo alone (administered at Days 1 and 31).

Reporting group values	RSV1D Group	RSV2D Group	Comparator_Placebo Group
Number of subjects	65	71	65
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)	65	71	65
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous			
Units: months			
arithmetic mean	6.4	6.5	6.5

standard deviation	± 0.5	± 0.5	± 0.5
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Sex: Female, Male			
Units: Participants			
Female	32	33	31
Male	33	38	34
Race/Ethnicity, Customized			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	1	1	2
ASIAN	1	1	1
BLACK OR AFRICAN AMERICAN	0	1	0
OTHER, Not specified	25	29	25
WHITE	38	39	37

Reporting group values	Total		
Number of subjects	201		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	201		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous			
Units: months			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: Participants			
Female	96		
Male	105		
Race/Ethnicity, Customized			
Units: Subjects			
AMERICAN INDIAN OR ALASKA NATIVE	4		
ASIAN	3		
BLACK OR AFRICAN AMERICAN	1		
OTHER, Not specified	79		
WHITE	114		

End points

End points reporting groups

Reporting group title	RSV1D Group
Reporting group description:	
Subjects received the interventions as follows: -Either 1 dose of experimental RSV (GSK3389245A) lower dose formulation at Day 1, followed by 1 dose of Placebo at Day 31 and any one the following active comparators: 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 61 and at the end of RSV season 1) or 3 doses of GSK's multicomponent meningococcal B vaccine or Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine or GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 61, 121 and at the end of RSV season 1). -Or 1 dose of experimental RSV (GSK3389245A) lower dose formulation at Day 1, followed by 1 dose of Placebo at Day 31.	
Reporting group title	RSV2D Group
Reporting group description:	
Subjects received the interventions as follows: -Either 2 doses of experimental RSV (GSK3389245A) higher dose formulation (administered at Day 1 and Day 31) and followed by any one the following active comparators: 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 61 and at the end of RSV season 1) or 3 doses of GSK's multicomponent meningococcal B vaccine or Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine or GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 61, 121 and at the end of RSV season 1). -Or 2 doses of experimental RSV (GSK3389245A) higher dose formulation administered at Day 1 and Day 31.	
Reporting group title	Comparator_Placebo Group
Reporting group description:	
Subjects received either one of interventions schedules as follows: -3 doses of GSK's multicomponent meningococcal B vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121). -3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121). -3 doses of GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 31, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Day 1 and Day 121). -2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 31 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 1 and 61) . -2 doses of Placebo alone (administered at Days 1 and 31).	
Subject analysis set title	Placebo Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received 2 doses of Placebo alone (administered at Days 1 and 31).	
Subject analysis set title	Active Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received either one of interventions schedule as follows: -3 doses of GSK's multicomponent meningococcal B vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121). -3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121). -3 doses of GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 31, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Day 1 and Day 121). -2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 31 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 1 and 61) .	
Subject analysis set title	Placebo Group
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received 2 doses of Placebo alone (administered at Days 1 and 31).	
Subject analysis set title	Active Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received either one of interventions schedule as follows:

-3 doses of GSK's multicomponent meningococcal B vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121).

-3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121).

-3 doses of GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 31, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Day 1 and Day 121).

-2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 31 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 1 and 61) .

Subject analysis set title	Bexsero Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received 3 doses of GSK's multicomponent meningococcal B vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121).

Subject analysis set title	Nimenrix Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received 3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121).

Subject analysis set title	Synflorix Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received 3 doses of GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 31, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Day 1 and Day 121).

Subject analysis set title	Menveo Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 31 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 1 and 61)

Subject analysis set title	Bexsero Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received 3 doses of GSK's multicomponent meningococcal B vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121).

Primary: Number of subjects with any solicited local adverse events (AEs) during a 7-day follow-up period after the first vaccination (administered at Day 1)

End point title	Number of subjects with any solicited local adverse events (AEs) during a 7-day follow-up period after the first vaccination (administered at Day 1) ^{[1][2]}
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End point description:

Assessed solicited local AEs are erythema, pain and swelling at injection site. Any = occurrence of the adverse event regardless of intensity grade. Any redness and swelling = adverse event reported with a surface diameter greater than 0 millimeters.

Analysis was performed on the Exposed set, which included all subjects with at least 1 study vaccine administration documented and diary card completed after first vaccination. Solicited local AEs were summarized by 4 groups to provide a comparison group with only placebo rather than a mixture of placebo and active comparators (Comparator_Placebo Group). Study interest was to collect solicited AEs during the follow-up period of study RSV vaccine, compared to placebo and routine pediatric vaccines.

End point type	Primary
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End point timeframe:

During a 7-day follow-up period after the first vaccination (administered at Day 1)

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Solicited local AEs were summarized by 4 groups to provide a comparison group with only placebo rather than a mixture of placebo and active comparators (Comparator Placebo Group). Study Investigator's interest was to check solicited AEs only during the follow-up period of experimental RSV vaccine.

End point values	RSV1D Group	RSV2D Group	Placebo Group	Active Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	65	71	22	42
Units: Subjects				
Any Erythema	5	6	0	22
Any Pain	11	10	1	17
Any Swelling	2	3	2	11

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any solicited local adverse events (AEs) during a 7-day follow-up period after the second vaccination (administered at Day 31)

End point title	Number of subjects with any solicited local adverse events (AEs) during a 7-day follow-up period after the second vaccination (administered at Day 31) ^{[3][4]}
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End point description:

End point type	Primary
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End point timeframe:

During a 7-day follow-up period after the second vaccination (administered at Day 31)

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Solicited local AEs were summarized by 4 groups to provide a comparison group with only placebo rather than a mixture of placebo and active comparators (Comparator Placebo Group). Study Investigator's interest was to check solicited AEs only during the follow-up period of experimental RSV vaccine.

End point values	RSV1D Group	RSV2D Group	Placebo Group	Active Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	63	71	20	41
Units: Subjects				
Any Erythema	8	7	0	11
Any Pain	5	9	0	6
Any Swelling	1	3	0	6

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any solicited general AEs during a 7-day follow-up period after the first vaccination (administered at Day 1)

End point title	Number of subjects with any solicited general AEs during a 7-day follow-up period after the first vaccination (administered at Day 1) ^[5] ^[6]
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End point description:

Assessed solicited general adverse events are drowsiness, fever [defined as temperature equal to or above (\geq) 38 degrees Celsius (C)/100.4 Fahrenheit (F) by any route], irritability/fussiness and loss of appetite. Any = occurrence of the adverse event regardless of intensity grade or relation to study vaccination.

Analysis was performed on the Exposed set, which included all subjects with at least 1 study vaccine administration documented and the diary card completed after first vaccination. Solicited general AEs were summarized by individual comparators (placebo, Bexsero, Nimenrix, Synflorix, Menveo) as the interest was to investigate solicited AEs during the follow-up period of study RSV vaccine, compared to placebo and routine pediatric vaccines, especially comparing to the rates of Bexsero-related fever.

End point type	Primary
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End point timeframe:

During a 7-day follow-up period after the first vaccination (administered at Day 1)

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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Solicited local AEs were summarized by 4 groups to provide a comparison group with only placebo rather than a mixture of placebo and active comparators (Comparator Placebo Group). Study Investigator's interest was to check solicited AEs only during the follow-up period of experimental RSV vaccine.

End point values	RSV1D Group	RSV2D Group	Placebo Group	Bexsero Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	65	71	22	28
Units: Subjects				
Any Drowsiness	12	19	7	11
Any Fever	9	24	5	11
Any Irritability/Fussiness	25	31	9	20
Any Loss of appetite	12	17	8	12

End point values	Nimenrix Group	Synflorix Group	Menveo Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	1	1	12	

Units: Subjects				
Any Drowsiness	0	1	2	
Any Fever	0	0	2	
Any Irritability/Fussiness	0	1	4	
Any Loss of appetite	0	0	2	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any solicited general AEs during a 7-day follow-up period after the second vaccination (administered at Day 31)

End point title	Number of subjects with any solicited general AEs during a 7-day follow-up period after the second vaccination (administered at Day 31) ^{[7][8]}
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End point description:

End point type	Primary
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End point timeframe:

During a 7-day follow-up period after the second vaccination (administered at Day 31)

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Solicited local AEs were summarized by 4 groups to provide a comparison group with only placebo rather than a mixture of placebo and active comparators (Comparator Placebo Group). Study Investigator's interest was to check solicited AEs only during the follow-up period of experimental RSV vaccine.

End point values	RSV1D Group	RSV2D Group	Placebo Group	Nimenrix Group
Subject group type	Reporting group	Reporting group	Subject analysis set	Subject analysis set
Number of subjects analysed	63	71	20	1
Units: Subjects				
Any Drowsiness	10	18	3	0
Any Fever	6	28	0	0
Any Irritability/Fussiness	18	33	3	0
Any Loss of appetite	7	22	3	0

End point values	Synflorix Group	Menveo Group	Bexsero Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	1	12	27	
Units: Subjects				
Any Drowsiness	0	4	5	
Any Fever	0	3	1	
Any Irritability/Fussiness	0	6	9	
Any Loss of appetite	0	4	4	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any unsolicited AEs

End point title	Number of subjects with any unsolicited AEs ^[9]
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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. Unsolicited AEs are 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 study vaccination.

The analysis was performed on the Exposed set, which included all subjects with at least one study vaccine administration documented. Study interest was to check unsolicited AEs only during the follow-up period of study RSV vaccine.

End point type	Primary
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End point timeframe:

During a 30-day follow-up period across the 2 vaccinations administered at Day 1 and Day 31

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	71	65	
Units: Subjects	34	45	36	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any serious adverse events (SAEs) from Day 1 up to Day 61

End point title	Number of subjects with any serious adverse events (SAEs) from Day 1 up to Day 61 ^[10]
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End point description:

Assessed serious adverse events (SAEs) include medical occurrences that resulted in death, were life-threatening, required hospitalization or prolongation of hospitalization or resulted in disability/incapacity. Any = occurrence of SAE regardless of intensity grade or relation to study vaccination.

End point type	Primary
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End point timeframe:

From Day 1 up to Day 61

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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	71	65	
Units: Subjects	3	3	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with episode of spontaneous or excessive bleeding (AE of special interest)

End point title	Number of subjects with episode of spontaneous or excessive bleeding (AE of special interest) ^[11]
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End point description:

Any episode of spontaneous or excessive bleeding if occurring after vaccination was to be fully investigated with a full range of hematological tests to identify the underlying cause and reported as an AE of special interest.

The analysis was performed on the Exposed set, which included all subjects with at least one study vaccine administration documented. Study interest was to check episode of spontaneous or excessive bleeding (AE of special interest) only during the follow-up period of study RSV vaccine.

End point type	Primary
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End point timeframe:

During a 30-day follow-up period across the 2 vaccinations administered at Day 1 and Day 31

Notes:

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

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	71	65	
Units: Subjects	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with respiratory tract infection associated with RSV infection (RSV-RTI), lower respiratory tract infection associated with RSV infection (RSV-LRTI), severe RSV-LRTI and very severe RSV-LRTI (according to standardized case definitions)

End point title	Number of subjects with respiratory tract infection associated with RSV infection (RSV-RTI), lower respiratory tract infection
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associated with RSV infection (RSV-LRTI), severe RSV-LRTI and very severe RSV-LRTI (according to standardized case definitions)

End point description:

According to standardized case definitions, RSV-RTI refers to subject having runny nose, OR blocked nose, OR cough AND confirmed RSV infection [RSV infection confirmed on nasal swab positive for RSV A or B by quantitative Reverse Transcription Polymerase Chain Reaction (qRT-PCR) performed at sponsor level].

RSV-LRTI refers to a subject having a history of cough OR difficulty breathing [based on history reported by parents] AND blood oxygen saturation (SpO2) lower than (<) 95 percent (%), OR respiratory rate (RR) increase [defined as RR higher than or equal to (\geq) 50 per (/) minute (for 2-11 months of age) and \geq 40/min (for 12 months of age or above)] AND confirmed RSV infection.

Severe RSV-LRTI are cases meeting the RSV-LRTI case definition AND an SpO2 < 93 %, OR lower chest wall in-drawing.

Very severe RSV-LRTI are cases meeting the case definition of RSV-LRTI AND an SpO2 <90%, OR inability to feed, OR failure to respond/unconscious.

End point type	Secondary
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End point timeframe:

From first vaccination (Day 1) up to the end of the first RSV transmission season (up to 1 year)

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	71	65	
Units: Subjects				
RSV-RTI	21	17	27	
RSV-LRTI	3	3	4	
Severe RSV-LRTI	1	1	3	
Very severe RSV-LRTI	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with RSV-RTI, RSV-LRTI, severe RSV-LRTI and very severe RSV-LRTI (according to standardized case definitions)

End point title	Number of subjects with RSV-RTI, RSV-LRTI, severe RSV-LRTI and very severe RSV-LRTI (according to standardized case definitions)
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End point description:

End point type	Secondary
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End point timeframe:

From first vaccination (Day 1) up to the end of the second RSV transmission season (up to 2 years)

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	71	65	
Units: Subjects				
RSV-RTI	23	18	30	
RSV-LRTI	3	3	4	
Severe RSV-LRTI	1	1	3	
Very severe RSV-LRTI	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAEs from first vaccination (Day 1) up to the end of the second RSV transmission season (up to 2 years)

End point title	Number of subjects with SAEs from first vaccination (Day 1) up to the end of the second RSV transmission season (up to 2 years)
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End point description:

End point type	Secondary
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End point timeframe:

From first vaccination (Day 1) up to the end of the second RSV transmission season (up to 2 years)

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	71	65	
Units: Subjects	7	11	3	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with RSV-LRTI (AE of special interest) from first vaccination (Day 1) up to the end of the first RSV transmission season (up to 1 year)

End point title	Number of subjects with RSV-LRTI (AE of special interest) from first vaccination (Day 1) up to the end of the first RSV transmission season (up to 1 year)
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End point description:

Subjects experiencing an LRTI associated with RSV infection were reported as AE of special interest. To identify RSV-LRTI for the purpose of AE of specific interest, the diagnosis was based on the investigators' clinical judgment taking into account the clinical history, the examination, relevant medical investigations and locally-available diagnostic test for RSV.

End point type	Secondary
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End point timeframe:

From first vaccination (Day 1) up to the end of the first RSV transmission season (up to 1 year)

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	71	65	
Units: Subjects	7	6	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with RSV-LRTI (AE of special interest) from first vaccination (Day 1) up to the end of the second RSV transmission season (up to 2 years)

End point title	Number of subjects with RSV-LRTI (AE of special interest) from first vaccination (Day 1) up to the end of the second RSV transmission season (up to 2 years)
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End point description:

End point type	Secondary
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End point timeframe:

From first vaccination (Day 1) up to the end of the second RSV transmission season (up to 2 years)

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	71	65	
Units: Subjects	7	6	7	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of RSV infected subjects with a negative RSV exposure status (at screening based on in-stream baseline serological testing) with very severe RSV-LRTI (according to standardized case definition)

End point title	Number of RSV infected subjects with a negative RSV exposure status (at screening based on in-stream baseline serological testing) with very severe RSV-LRTI (according to standardized case definition)
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End point description:

Very severe RSV LRTI are cases meeting the case definition of RSV-LRTI AND a SpO2 <90%, OR

inability to feed, OR failure to respond/unconscious.

The analysis was performed on the Exposed set with a negative RSV exposure status, which included all vaccinated subjects assessed as RSV unexposed at screening based on in-stream baseline serological testing.

End point type	Secondary
End point timeframe:	
From first vaccination (Day 1) up to the end of the first RSV transmission season (up to 1 year)	

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	49	58	52	
Units: Subjects	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-RSV-A neutralizing antibody titers

End point title	Anti-RSV-A neutralizing antibody titers
End point description:	
Humoral response to the investigational RSV vaccine was measured in terms of anti-RSV-A neutralizing antibody titers and expressed as geometric mean titers (GMTs) in Estimated Dilution 60 (ED60) titers. The analysis was performed on the Per-protocol set for analysis of immunogenicity, which included all subjects with at least one study vaccine administration documented, who complied with eligibility criteria, study procedures up to the end of the study and had immunogenicity results for the specified assay and time point.	
End point type	Secondary
End point timeframe:	
At pre-vaccination (Screening), Day 31, Day 61 and at the end of the first RSV transmission season (EOS1) (up to 1 year)	

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	71	61	
Units: Titers				
geometric mean (confidence interval 95%)				
Screening (N=64,71,61)	26.8 (20.7 to 34.6)	29.6 (23.6 to 37.3)	32.2 (24.9 to 41.6)	
Day 31 (N=63,69,61)	60.2 (44.2 to 81.9)	116.2 (87.6 to 153.9)	18.9 (14.8 to 24.1)	
Day 61 (N=63,70,56)	54.3 (37.7 to 78)	259.4 (211.6 to 318.1)	14.4 (11.8 to 17.7)	
EOS1 (N=60,70,61)	165 (95 to 286.6)	223.7 (154.7 to 323.4)	66.3 (40.2 to 109.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-RSV-F antibody concentrations

End point title	Anti-RSV-F antibody concentrations
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End point description:

Humoral response to the investigational RSV vaccine was measured in terms of anti-RSV-F antibody concentrations and expressed as geometric mean concentrations (GMCs) in enzyme-linked immunosorbent assay (ELISA) units per milliliter (EU/mL).

The analysis was performed on the Per-protocol set for analysis of immunogenicity, which included all subjects with at least one study vaccine administration documented, who complied with eligibility criteria, study procedures up to the end of the study and had immunogenicity results for the specified assay and time point.

End point type	Secondary
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End point timeframe:

At pre-vaccination (Screening), Day 31, Day 61 and at the end of the first RSV transmission season (EOS1) (up to 1 year)

End point values	RSV1D Group	RSV2D Group	Comparator_Placebo Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	71	61	
Units: EU/mL				
geometric mean (confidence interval 95%)				
Screening (N=63,71,61)	93.1 (72.7 to 119.1)	81.9 (61.8 to 108.6)	86 (65.5 to 112.7)	
Day 31 (N=64,70,60)	2035.2 (1490 to 2779.9)	4550.8 (3354.6 to 6173.7)	46.2 (31.6 to 67.6)	
Day 61 (N=61,70,55)	1976.5 (1346.2 to 2901.8)	9287.9 (7885.5 to 10939.7)	24.6 (18.3 to 33)	
EOS1 (N=60,69,60)	5108.7 (3096.7 to 8428)	4935.5 (3639.8 to 6692.4)	345.1 (165.9 to 717.7)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected during the 7-day follow-up period and unsolicited AEs during the 30-day follow-up period after any vaccination. SAEs were collected from Day 1 up to the end of the second RSV transmission season (up to 2 years).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	RSV1D Group
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Reporting group description:

Subjects received the interventions as follows: -Either 1 dose of experimental RSV (GSK3389245A) lower dose formulation at Day 1, followed by 1 dose of Placebo at Day 31 and any one the following active comparators: 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 61 and at the end of RSV season 1) or 3 doses of GSK's multicomponent meningococcal B vaccine or Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine or GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 61, 121 and at the end of RSV season 1). -Or 1 dose of experimental RSV (GSK3389245A) lower dose formulation at Day 1, followed by 1 dose of Placebo at Day 31.

Reporting group title	Comparator_Placebo Group
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Reporting group description:

Subjects received either one of interventions schedules as follows: -3 doses of GSK's multicomponent meningococcal B vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121). -3 doses of Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Days 1, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 31 and 121). -3 doses of GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 31, 61 and at the end of RSV season 1) and 2 doses of Placebo (administered at Day 1 and Day 121). -2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 31 and at the end of RSV season 1) and 2 doses of Placebo (administered at Days 1 and 61). -2 doses of Placebo alone (administered at Days 1 and 31).

Reporting group title	RSV2D Group
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Reporting group description:

Subjects received the interventions as follows: -Either 2 doses of experimental RSV (GSK3389245A) higher dose formulation (administered at Day 1 and Day 31) and followed by any one the following active comparators: 2 doses of GSK's meningococcal group A, C, W-135 and Y conjugate vaccine (administered at Day 61 and at the end of RSV season 1) or 3 doses of GSK's multicomponent meningococcal B vaccine or Pfizer's meningococcal group A, C, W-135 and Y conjugate vaccine or GSK's pneumococcal polysaccharide conjugate vaccine (administered at Days 61, 121 and at the end of RSV season 1). -Or 2 doses of experimental RSV (GSK3389245A) higher dose formulation administered at Day 1 and Day 31.

Serious adverse events	RSV1D Group	Comparator_Placebo Group	RSV2D Group
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 65 (10.77%)	3 / 65 (4.62%)	11 / 71 (15.49%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Foreign body in respiratory tract			

subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess neck			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	2 / 65 (3.08%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			

subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
H1N1 influenza			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infectious mononucleosis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection viral			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parvovirus infection			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	2 / 71 (2.82%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia respiratory syncytial viral			

subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	RSV1D Group	Comparator_Placebo Group	RSV2D Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	57 / 65 (87.69%)	57 / 65 (87.69%)	67 / 71 (94.37%)
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	17 / 65 (26.15%)	23 / 65 (35.38%)	37 / 71 (52.11%)
occurrences (all)	18	25	54
Administration site erythema			
subjects affected / exposed	9 / 65 (13.85%)	26 / 65 (40.00%)	11 / 71 (15.49%)
occurrences (all)	13	33	13
Administration site pain			
subjects affected / exposed	13 / 65 (20.00%)	19 / 65 (29.23%)	12 / 71 (16.90%)
occurrences (all)	16	24	19
Administration site swelling			

subjects affected / exposed occurrences (all)	3 / 65 (4.62%) 3	18 / 65 (27.69%) 19	4 / 71 (5.63%) 6
Injection site bruising subjects affected / exposed occurrences (all)	1 / 65 (1.54%) 1	0 / 65 (0.00%) 0	2 / 71 (2.82%) 2
Chills subjects affected / exposed occurrences (all)	1 / 65 (1.54%) 1	0 / 65 (0.00%) 0	0 / 71 (0.00%) 0
Feeling hot subjects affected / exposed occurrences (all)	0 / 65 (0.00%) 0	0 / 65 (0.00%) 0	1 / 71 (1.41%) 1
Immune system disorders Drug hypersensitivity subjects affected / exposed occurrences (all)	1 / 65 (1.54%) 1	0 / 65 (0.00%) 0	0 / 71 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Hypopnoea subjects affected / exposed occurrences (all)	1 / 65 (1.54%) 2	0 / 65 (0.00%) 0	0 / 71 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 65 (0.00%) 0	0 / 65 (0.00%) 0	1 / 71 (1.41%) 1
Nasal congestion subjects affected / exposed occurrences (all)	0 / 65 (0.00%) 0	0 / 65 (0.00%) 0	1 / 71 (1.41%) 1
Sneezing subjects affected / exposed occurrences (all)	0 / 65 (0.00%) 0	0 / 65 (0.00%) 0	1 / 71 (1.41%) 1
Psychiatric disorders Irritability subjects affected / exposed occurrences (all)	34 / 65 (52.31%) 44	36 / 65 (55.38%) 53	41 / 71 (57.75%) 65
Insomnia subjects affected / exposed occurrences (all)	1 / 65 (1.54%) 1	0 / 65 (0.00%) 0	0 / 71 (0.00%) 0
Sleep disorder			

subjects affected / exposed occurrences (all)	0 / 65 (0.00%) 0	0 / 65 (0.00%) 0	1 / 71 (1.41%) 1
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	2 / 71 (2.82%)
occurrences (all)	0	1	2
Head injury			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Congenital, familial and genetic disorders			
Congenital pulmonary valve atresia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Somnolence			
subjects affected / exposed	18 / 65 (27.69%)	26 / 65 (40.00%)	29 / 71 (40.85%)
occurrences (all)	22	33	37
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	1 / 71 (1.41%)
occurrences (all)	0	1	1
Monocytosis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 65 (6.15%)	4 / 65 (6.15%)	3 / 71 (4.23%)
occurrences (all)	4	6	3
Vomiting			
subjects affected / exposed	4 / 65 (6.15%)	2 / 65 (3.08%)	4 / 71 (5.63%)
occurrences (all)	4	2	5
Teething			
subjects affected / exposed	4 / 65 (6.15%)	1 / 65 (1.54%)	4 / 71 (5.63%)
occurrences (all)	4	2	4
Constipation			

subjects affected / exposed	1 / 65 (1.54%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Gingival pain			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Mucous stools			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hepatosplenomegaly			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	4 / 65 (6.15%)	3 / 65 (4.62%)	2 / 71 (2.82%)
occurrences (all)	5	3	2
Rash			
subjects affected / exposed	2 / 65 (3.08%)	0 / 65 (0.00%)	2 / 71 (2.82%)
occurrences (all)	2	0	2
Dermatitis contact			
subjects affected / exposed	2 / 65 (3.08%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Eczema			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	1	0	1
Dry skin			

subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	12 / 65 (18.46%)	15 / 65 (23.08%)	13 / 71 (18.31%)
occurrences (all)	14	19	15
Upper respiratory tract infection			
subjects affected / exposed	4 / 65 (6.15%)	5 / 65 (7.69%)	8 / 71 (11.27%)
occurrences (all)	6	5	11
Gastroenteritis			
subjects affected / exposed	3 / 65 (4.62%)	2 / 65 (3.08%)	7 / 71 (9.86%)
occurrences (all)	3	2	7
Otitis media acute			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	3 / 71 (4.23%)
occurrences (all)	0	1	4
Rhinitis			
subjects affected / exposed	1 / 65 (1.54%)	2 / 65 (3.08%)	0 / 71 (0.00%)
occurrences (all)	1	2	0
Otitis media			
subjects affected / exposed	2 / 65 (3.08%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	2	0	1
Hand-foot-and-mouth disease			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	2 / 71 (2.82%)
occurrences (all)	0	1	2
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	2 / 71 (2.82%)
occurrences (all)	1	0	2
Gastroenteritis viral			
subjects affected / exposed	1 / 65 (1.54%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	1	1	0

Impetigo			
subjects affected / exposed	1 / 65 (1.54%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Oral candidiasis			
subjects affected / exposed	1 / 65 (1.54%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Pharyngitis			
subjects affected / exposed	1 / 65 (1.54%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Respiratory syncytial virus infection			
subjects affected / exposed	1 / 65 (1.54%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	1	1	0
Acarodermatitis			
subjects affected / exposed	2 / 65 (3.08%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Bronchitis			
subjects affected / exposed	2 / 65 (3.08%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	4	0	0
Tonsillitis			
subjects affected / exposed	2 / 65 (3.08%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	2	0	0
Influenza			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	1	0	1
Lower respiratory tract infection			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	2	0	1
Pyoderma			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	1 / 71 (1.41%)
occurrences (all)	0	1	1
Respiratory tract infection viral			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	1 / 71 (1.41%)
occurrences (all)	0	1	1
Bronchiolitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	0	1	0

Conjunctivitis			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Exanthema subitum			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Herpangina			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Otitis externa			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Respiratory syncytial virus bronchiolitis			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 65 (0.00%)	1 / 65 (1.54%)	0 / 71 (0.00%)
occurrences (all)	0	1	0
Viral infection			
subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0
Croup infectious			
subjects affected / exposed	0 / 65 (0.00%)	0 / 65 (0.00%)	1 / 71 (1.41%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	17 / 65 (26.15%)	25 / 65 (38.46%)	32 / 71 (45.07%)
occurrences (all)	19	33	39
Malnutrition			

subjects affected / exposed	1 / 65 (1.54%)	0 / 65 (0.00%)	0 / 71 (0.00%)
occurrences (all)	1	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 July 2018	Clarification added that the study will evaluate 2 regimens of the investigational vaccine. Synflorix vaccine was added as one of the potential active comparator vaccines to be considered in the countries where it is currently licensed.
24 January 2019	Clarification added that hypersensitivity to any component of comparator or control vaccines used in this study or contraindication to them is an exclusion criterion.
21 March 2019	Indication of Pneumonia was added for Synflorix. Exclusion criteria related to mothers participating in another clinical study was clarified to specified if breast-feeding. Cut off values for neutralization assay was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported