

**Clinical trial results:**

A Phase II, randomised, observer-blind, controlled, multi-country study to assess the safety, reactogenicity and immunogenicity of a single intramuscular dose of different formulations of GlaxoSmithKline (GSK) Biologicals' investigational RSV vaccine (GSK3003891A), in healthy women aged 18 to 45 years

Summary

EudraCT number	2014-002688-14
Trial protocol	CZ DE
Global end of trial date	21 June 2016

Results information

Result version number	v2 (current)
This version publication date	04 November 2020
First version publication date	29 June 2017
Version creation reason	<ul style="list-style-type: none">• Correction of full data set Results have been amended to account for consistency with other registries.

Trial information**Trial identification**

Sponsor protocol code	201510
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02360475
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?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	08 November 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 July 2015
Global end of trial reached?	Yes
Global end of trial date	21 June 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the reactogenicity and the safety of a single intramuscular dose of the investigational RSV vaccines, in healthy, non-pregnant women, during the first 30 days after vaccination.

To evaluate the functional antibody titres induced by a single intramuscular dose of the investigational RSV vaccines, in healthy, non-pregnant women, 30 days after vaccination.

Protection of trial subjects:

The body temperature of the subject was determined prior to study vaccination. If a subject had fever on the day of planned vaccination, the vaccination visit was rescheduled. All subjects were supervised closely for at least 30 minutes following vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications. Subjects were followed for one year following administration of the study vaccine.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 March 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	Czech Republic: 125
Country: Number of subjects enrolled	Germany: 126
Country: Number of subjects enrolled	Australia: 125
Country: Number of subjects enrolled	United States: 131
Worldwide total number of subjects	507
EEA total number of subjects	251

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)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	507
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 507 subjects were screened, but only 500 subjects received vaccination.

Pre-assignment

Screening details:

NA

Period 1

Period 1 title	Overall study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Given the different appearance and presentation of the investigational RSV vaccines, and Boostrix, double blinding was not possible and data was collected in an observer-blind manner: during the course of the study, the vaccine recipient and those responsible for the evaluation of any study endpoint were unaware of which vaccine was administered.

Arms

Are arms mutually exclusive?	Yes
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Arm title	GSK3003891A 30 Non-adjuvanted Group
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Arm description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of the non-adjuvanted 30 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Arm type	Experimental
Investigational medicinal product name	GSK3003891A non-adjuvanted 30 µg PreF
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single dose of GSK3003891A non-adjuvanted 30 µg PreF vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Arm title	GSK3003891A 60 Non-adjuvanted Group
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Arm description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of non-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Arm type	Experimental
Investigational medicinal product name	GSK3003891A 60 PreF Group
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solution for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single dose of GSK3003891A non-adjuvanted 60 µg PreF vaccine, intramuscularly in the deltoid region of the non-dominant arm, at Day 0.

Arm title	GSK3003891A 60 Adjuvanted Group
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Arm description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of aluminium-adsorbed 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Arm type	Experimental
Investigational medicinal product name	GSK3003891A 60 PreF-AI Group
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single dose of RSV GSK3003891A aluminium-adsorbed 60 µg Pref vaccine, intramuscularly in the deltoid region of the non-dominant arm, at Day 0.

Arm title	Boostrix Group
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Arm description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of Boostrix™ vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Arm type	Active comparator
Investigational medicinal product name	Boostrix™
Investigational medicinal product code	
Other name	dTpa/Tdap
Pharmaceutical forms	Suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a single dose of Boostrix™ vaccine, intramuscularly in the deltoid region of the non-dominant arm, at Day 0.

Number of subjects in period 1^[1]	GSK3003891A 30 Non-adsorbed Group	GSK3003891A 60 Non-adsorbed Group	GSK3003891A 60 Adjuvanted Group
Started	126	124	125
Completed	122	111	117
Not completed	4	13	8
Consent withdrawn by subject	-	1	2
Migrated/moved from study area	-	-	-
Lost to follow-up	4	12	6

Number of subjects in period 1^[1]	Boostrix Group
Started	125
Completed	120
Not completed	5
Consent withdrawn by subject	-
Migrated/moved from study area	1
Lost to follow-up	4

Notes:

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

Justification: A total of 507 subjects were screened, but only 500 subjects received vaccination.

Baseline characteristics

Reporting groups

Reporting group title	GSK3003891A 30 Non-adjuvanted Group
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Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of the non-adjuvanted 30 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Reporting group title	GSK3003891A 60 Non-adjuvanted Group
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Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of non-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Reporting group title	GSK3003891A 60 Adjuvanted Group
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Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of aluminium-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Reporting group title	Boostrix Group
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Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of Boostrix™ vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Reporting group values	GSK3003891A 30 Non-adjuvanted Group	GSK3003891A 60 Non-adjuvanted Group	GSK3003891A 60 Adjuvanted Group
Number of subjects	126	124	125
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	29.2	29.5	29.1
standard deviation	± 7.5	± 8.2	± 7.4
Gender categorical Units: Subjects			
Female	126	124	125
Male	0	0	0

Reporting group values	Boostrix Group	Total	
Number of subjects	125	500	

Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		0	
Newborns (0-27 days)		0	
Infants and toddlers (28 days-23 months)		0	
Children (2-11 years)		0	
Adolescents (12-17 years)		0	
Adults (18-64 years)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	29.2		
standard deviation	± 7.9	-	
Gender categorical Units: Subjects			
Female	125	500	
Male	0	0	

End points

End points reporting groups

Reporting group title	GSK3003891A 30 Non-adjuvanted Group
Reporting group description: Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of the non-adjuvanted 30 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.	
Reporting group title	GSK3003891A 60 Non-adjuvanted Group
Reporting group description: Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of non-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.	
Reporting group title	GSK3003891A 60 Adjuvanted Group
Reporting group description: Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of aluminium-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.	
Reporting group title	Boostrix Group
Reporting group description: Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of Boostrix™ vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.	

Primary: Number of subjects with solicited local symptoms

End point title	Number of subjects with solicited local symptoms ^[1]
End point description: Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = Significant pain at rest, pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling with a maximum diameter greater than 100 millimeters (mm).	
End point type	Primary
End point timeframe: During the 7-day (Days 0-6) post-vaccination period	
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 end point was descriptive, no statistical hypothesis test was performed.	

End point values	GSK3003891A 30 Non-adjuvanted Group	GSK3003891A 60 Non-adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	119	124	124
Units: Subjects				
Any Pain	62	68	104	104
Grade 3 Pain	1	2	9	3
Any Redness	6	3	8	6
Grade 3 Redness	0	0	0	0
Any Swelling	7	6	12	5
Grade 3 Swelling	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited general symptoms

End point title	Number of subjects with solicited general symptoms ^[2]
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End point description:

Assessed solicited general symptoms (symp.) were headache, fever [defined as oral temperature (temp.) equal to or above 37.5 degrees Celsius (°C)], fatigue, gastrointestinal (Gastro.) symptoms [nausea, vomiting, diarrhoea and/or abdominal pain]. Any = occurrence of the symptom regardless of intensity grade and relationship. Grade 3 (G3) symptom = symptom that prevented normal activity. Grade 3 fever = fever > 39.5 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Primary
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End point timeframe:

During the 7-day (Days 0-6) post-vaccination period

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 end point was descriptive, no statistical hypothesis test was performed.

End point values	GSK3003891A 30 Non- adjuvanted Group	GSK3003891A 60 Non- adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	119	124	124
Units: Subjects				
Any Fatigue	53	50	56	45
G3 Fatigue	8	1	4	2
Related Fatigue	44	41	50	39
Any Gastro. symp.	16	19	23	20
G3 Gastro. symp.	1	2	1	0
Related Gastro. symp.	9	14	21	17
Any Headache	47	44	53	39
G3 Headache	3	2	5	3
Related Headache	37	33	39	33
Any Temp.	7	9	12	7
G3 Temp.	0	0	0	0
Related Temp.	5	8	11	6

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with unsolicited adverse events (AEs) ^[3]
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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 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.

End point type	Primary
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End point timeframe:

During the 30-Day (Days 0-29) post-vaccination period

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 end point was descriptive, no statistical hypothesis test was performed.

End point values	GSK3003891A 30 Non- adjuvanted Group	GSK3003891A 60 Non- adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	124	125	125
Units: Subjects				
Any AE(s)	35	38	34	37

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with serious adverse events (SAEs) ^[4]
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End point description:

Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.

End point type	Primary
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End point timeframe:

From vaccination at Day 0, up to Day 30 post-vaccination

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 end point was descriptive, no statistical hypothesis test was performed.

End point values	GSK3003891A 30 Non- adjuvanted Group	GSK3003891A 60 Non- adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	124	125	125
Units: Subjects				
Any SAE(s)	1	1	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Titres of RSV-A neutralizing antibodies

End point title	Titres of RSV-A neutralizing antibodies ^[5]
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End point description:

RSV-A neutralizing antibody titres, expressed as Geometric Mean Titres (GMTs). Seropositive subjects were defined as subjects whose antibody titre was greater than or equal to (\geq) the cut-off 8 serum dilution that induced 60 % inhibition in plaque forming units (ED60).

End point type	Primary
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End point timeframe:

At Day 0 pre-vaccination

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 end point was descriptive, no statistical hypothesis test was performed.

End point values	GSK3003891A 30 Non- adjuvanted Group	GSK3003891A 60 Non- adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	117	118	118
Units: Titers				
geometric mean (confidence interval 95%)				
anti-RSV A neutralizing antibodies	397.1 (330.7 to 476.7)	326.3 (277.1 to 384.4)	444.2 (370.4 to 532.6)	423.7 (360.2 to 498.4)

Statistical analyses

No statistical analyses for this end point

Primary: Titres of RSV-A neutralizing antibodies

End point title	Titres of RSV-A neutralizing antibodies ^[6]
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End point description:

RSV-A neutralizing antibody titres, expressed as Geometric Mean Titres (GMTs). Seropositive subjects were defined as subjects whose antibody titre was greater than or equal to (\geq) the cut-off 8 serum dilution that induced 60 % inhibition in plaque forming units (ED60).

End point type	Primary
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End point timeframe:

At Day 30 post-vaccination

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 end point was descriptive, no statistical hypothesis test was performed.

End point values	GSK3003891A 30 Non- adjuvanted Group	GSK3003891A 60 Non- adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	117	117	118	118
Units: Titers				
geometric mean (confidence interval 95%)				
anti-RSV A neutralizing antibodies	1237 (1094.8 to 1397.6)	1278.7 (1141.6 to 1432.2)	1442.5 (1287.4 to 1616.2)	387.1 (328.4 to 456.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Titres of RSV-A neutralizing antibodies

End point title	Titres of RSV-A neutralizing antibodies
End point description: RSV-A neutralizing antibody titres, expressed as Geometric Mean Titres (GMTs), were defined as any titre greater than or equal to (\geq) the cut-off 8 serum dilution inducing 60 % inhibition in plaque forming units (ED60).	
End point type	Secondary
End point timeframe: At Day 60 (D60) and 90 (D90) post-vaccination	

End point values	GSK3003891A 30 Non- adjuvanted Group	GSK3003891A 60 Non- adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	112	111	110	111
Units: Titers				
geometric mean (confidence interval 95%)				
anti-RSV A, D60 [N=109;111;108;111]	947.2 (832.9 to 1077.1)	882.9 (781.9 to 996.9)	1055.7 (926.1 to 1203.4)	358.8 (297.8 to 432.3)
anti-RSV A, D90 [N=112;111;110;111]	837.7 (738.9 to 949.7)	774.5 (682.6 to 878.7)	897.5 (782.8 to 1029.2)	358.3 (291.9 to 439.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Concentrations of Palivizumab competing antibodies (PCA)

End point title	Concentrations of Palivizumab competing antibodies (PCA)
End point description: PCA concentrations, expressed as Geometric Mean Concentrations (GMCs).The assay cut-off was greater than or equal to 3.34 micrograms per millilitre (µg/mL).	
End point type	Secondary
End point timeframe: At Day 0 (D0) pre-vaccination, Day 30 (D30), Day 60 (D60) and Day 90 (D90) post-vaccination	

End point values	GSK3003891A 30 Non- adjuvanted Group	GSK3003891A 60 Non- adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	115	111	116	111
Units: µg/mL				
geometric mean (confidence interval 95%)				
anti-PCA, D0 [N=110;107;105;110]	5.4 (4.7 to 6.3)	5.2 (4.4 to 6)	4.6 (4 to 5.4)	5.7 (4.8 to 6.7)
anti-PCA, D30 [N=115;116;116;109]	79.9 (72.1 to 88.6)	88.6 (79.9 to 98.2)	97.2 (89.1 to 105.9)	6.1 (5.3 to 7.1)
anti-PCA,D60 [N=109;111;108;111]	65.9 (57.8 to 75.1)	68.4 (61.5 to 75.9)	74.1 (66.6 to 82.3)	5.8 (5 to 6.7)
anti-PCA, D90 [N=112;111;110;109]	60.4 (54 to 67.6)	62.5 (56.7 to 68.9)	66.1 (59.9 to 73)	7.5 (6.6 to 8.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAEs

End point title	Number of subjects with SAEs
End point description: SAEs assessed include medical occurrences that result in death, are life-threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity.	
End point type	Secondary
End point timeframe: Up to study end at Day 360	

End point values	GSK3003891A 30 Non- adjuvanted Group	GSK3003891A 60 Non- adjuvanted Group	GSK3003891A 60 Adjuvanted Group	Boostrix Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	126	124	125	125
Units: Subjects				
Any SAE(s)	3	3	6	2

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited and Unsolicited AEs: within the 30-day (Days 0-29) post-vaccination period; SAEs: from Day 0 up to study end at Day 360.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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Reporting groups

Reporting group title	GSK3003891A 30 Non-adjuvanted Group
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Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of the non-adjuvanted 30 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Reporting group title	GSK3003891A 60 Non-adjuvanted Group
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Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of non-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Reporting group title	GSK3003891A 60 Adjuvanted Group
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Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of aluminium-adjuvanted 60 µg investigational GSK3003891A vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Reporting group title	Boostrix Group
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Reporting group description:

Healthy non-pregnant female subjects between and including 18 and 45 years of age at the time of vaccination received a single dose of Boostrix™ vaccine, intramuscularly, in the deltoid region of the non-dominant arm, at Day 0.

Serious adverse events	GSK3003891A 30 Non-adjuvanted Group	GSK3003891A 60 Non-adjuvanted Group	GSK3003891A 60 Adjuvanted Group
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 126 (2.38%)	3 / 124 (2.42%)	6 / 125 (4.80%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Multiple injuries			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal injury			

subjects affected / exposed	0 / 126 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Fibula fracture			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incisional hernia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tibia fracture			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 126 (0.00%)	1 / 124 (0.81%)	0 / 125 (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
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 126 (0.00%)	1 / 124 (0.81%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Umbilical hernia			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obliterative bronchiolitis			
subjects affected / exposed	1 / 126 (0.79%)	0 / 124 (0.00%)	0 / 125 (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			
Suicide attempt			
subjects affected / exposed	1 / 126 (0.79%)	0 / 124 (0.00%)	0 / 125 (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
Musculoskeletal and connective tissue disorders			
Jaw cyst			
subjects affected / exposed	1 / 126 (0.79%)	0 / 124 (0.00%)	0 / 125 (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
Infections and infestations			
Pneumonia bacterial			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	0 / 125 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Erysipelas			
subjects affected / exposed	0 / 126 (0.00%)	0 / 124 (0.00%)	1 / 125 (0.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Boostrix Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 125 (1.60%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			

Injury, poisoning and procedural complications			
Multiple injuries			
subjects affected / exposed	1 / 125 (0.80%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal injury			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fibula fracture			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incisional hernia			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Tibia fracture			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis			

subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Umbilical hernia			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Obliterative bronchiolitis			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Jaw cyst			
subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Pneumonia bacterial			
subjects affected / exposed	1 / 125 (0.80%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erysipelas			

subjects affected / exposed	0 / 125 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	GSK3003891A 30 Non-adjuvanted Group	GSK3003891A 60 Non-adjuvanted Group	GSK3003891A 60 Adjuvanted Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	93 / 126 (73.81%)	88 / 124 (70.97%)	112 / 125 (89.60%)
Nervous system disorders			
Headache			
subjects affected / exposed	49 / 126 (38.89%)	45 / 124 (36.29%)	56 / 125 (44.80%)
occurrences (all)	53	47	59
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	53 / 126 (42.06%)	50 / 124 (40.32%)	56 / 125 (44.80%)
occurrences (all)	53	50	57
Pain			
subjects affected / exposed	62 / 126 (49.21%)	68 / 124 (54.84%)	104 / 125 (83.20%)
occurrences (all)	62	69	105
Pyrexia			
subjects affected / exposed	7 / 126 (5.56%)	10 / 124 (8.06%)	12 / 125 (9.60%)
occurrences (all)	7	10	12
Swelling			
subjects affected / exposed	7 / 126 (5.56%)	6 / 124 (4.84%)	12 / 125 (9.60%)
occurrences (all)	7	6	12
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	16 / 126 (12.70%)	19 / 124 (15.32%)	23 / 125 (18.40%)
occurrences (all)	16	19	23
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	6 / 126 (4.76%)	3 / 124 (2.42%)	8 / 125 (6.40%)
occurrences (all)	6	3	8
Infections and infestations			

Upper respiratory tract infection subjects affected / exposed occurrences (all)	2 / 126 (1.59%) 2	7 / 124 (5.65%) 7	3 / 125 (2.40%) 3
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Non-serious adverse events	Boostrix Group		
Total subjects affected by non-serious adverse events subjects affected / exposed	109 / 125 (87.20%)		
Nervous system disorders Headache subjects affected / exposed occurrences (all)	41 / 125 (32.80%) 43		
General disorders and administration site conditions Fatigue subjects affected / exposed occurrences (all) Pain subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all) Swelling subjects affected / exposed occurrences (all)	45 / 125 (36.00%) 46 104 / 125 (83.20%) 104 8 / 125 (6.40%) 8 5 / 125 (4.00%) 5		
Gastrointestinal disorders Gastrointestinal disorder subjects affected / exposed occurrences (all)	20 / 125 (16.00%) 20		
Skin and subcutaneous tissue disorders Erythema subjects affected / exposed occurrences (all)	6 / 125 (4.80%) 6		
Infections and infestations Upper respiratory tract infection subjects affected / exposed occurrences (all)	6 / 125 (4.80%) 6		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 February 2015	<p>Following US Food and Drug Administration (FDA) feedback on the RSV F-020 (201510) protocol, the following changes were implemented:</p> <p>Addition of a one-year safety phone call to collect information about any serious adverse events (SAEs) and pregnancies that may have occurred between Visit 4 (Day 90) and the Phone contact (Day 360).</p> <p>Section 8.1.4 has been updated to clarify that clinical safety laboratory testing is not required per protocol unless the investigator believes it is warranted. Any abnormal laboratory findings (e.g. clinical chemistry, haematology, urinalysis) or other abnormal assessments that are judged by the investigator to be clinically significant will be recorded as AE or SAE if they meet the definition of an AE or SAE.</p> <p>In addition, the list of contributing authors was updated.</p>

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported