Clinical trial results:
A phase II, randomised, observer-blind, controlled, study to assess the reactogenicity and safety of a single intramuscular dose of GlaxoSmithKline (GSK) Biologicals' investigational respiratory syncytial virus (RSV) vaccine (GSK3003891A) in 18 to 45 year-old healthy non-pregnant women.

Summary

EudraCT number	2015-005742-58
Trial protocol	BE
Global end of trial date	28 June 2016

Results information

Result version number	v1 (current)
This version publication date	29 June 2017
First version publication date	29 June 2017

Trial information

Trial identification

Sponsor protocol code	204813

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02753413
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	09 September 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 June 2016
Global end of trial reached?	Yes
Global end of trial date	28 June 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the reactogenicity and safety of a single dose of the investigational RSV vaccine in healthy non-pregnant women during the study period.

Protection of trial subjects:

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 to any components of the vaccines. Subjects were followed-up for one month (minimum 30 days) following administration of the study vaccine.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 April 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 102
Worldwide total number of subjects	102
EEA total number of subjects	102

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)	102
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 102 subject numbers were screened, but only 100 subjects were randomized and received vaccination.

Pre-assignment

Screening details:

NA

Period 1

Period 1 title	Overall Period (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 vaccine, 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. Vaccine preparation and administration was done by authorised medical personnel who did not participate in any of the study clinical evaluation assays.

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK3003891A Group

Arm description:

Healthy, non-pregnant women, aged 18-45 at the time of vaccination, were administered one dose of the investigational GSK3003891A vaccine, intramuscularly in the deltoid region of the arm, at Day 0

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

Dosage and administration details:

Subjects were administered one dose of the investigational GSK3003891A vaccine, intramuscularly in the deltoid region of the arm, at Day 0.

Arm title	Boostrix Group

Arm description:

Healthy, non-pregnant women, aged 18-45 at the time of vaccination, were administered one dose of the comparator Boostrix™ vaccine, intramuscularly in the deltoid region of the arm, at Day 0.

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

Dosage and administration details:

Subjects were administered one dose of the comparator Boostrix™ vaccine, intramuscularly in the deltoid region of the arm, at Day 0.

Number of subjects in period 1[1]	GSK3003891A Group	Boostrix Group
Started	49	51
Completed	49	51

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 102 subject numbers were screened, but only 100 subjects were randomized and received vaccination.

Baseline characteristics

Reporting groups	
Reporting group title	GSK3003891A Group
Reporting group description:	
Healthy, non-pregnant women, aged 18-45 at the time of vaccination, were administered one dose of the investigational GSK3003891A vaccine, intramuscularly in the deltoid region of the arm, at Day 0	
Reporting group title	Boostrix Group
Reporting group description:	
Healthy, non-pregnant women, aged 18-45 at the time of vaccination, were administered one dose of the comparator Boostrix™ vaccine, intramuscularly in the deltoid region of the arm, at Day 0.	

Reporting group values	GSK3003891A Group	Boostrix Group	Total
Number of subjects	49	51	100
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	25.8	25.6	
standard deviation	± 5.9	± 6.1	-
Gender categorical			
Units: Subjects			
Female	49	51	100
Male	0	0	0

End points

End points reporting groups

Reporting group title	GSK3003891A Group

Reporting group description:

Healthy, non-pregnant women, aged 18-45 at the time of vaccination, were administered one dose of the investigational GSK3003891A vaccine, intramuscularly in the deltoid region of the arm, at Day 0

Reporting group title	Boostrix Group

Reporting group description:

Healthy, non-pregnant women, aged 18-45 at the time of vaccination, were administered one dose of the comparator Boostrix™ vaccine, intramuscularly in the deltoid region of the arm, at Day 0.

Primary: Number of subjects with abnormal biochemical laboratory parameter values by maximum grading

End point title	Number of subjects with abnormal biochemical laboratory parameter values by maximum grading[1]

End point description:

Among biochemical parameters tested were ALT, AST and CRE, graded by FDA toxicity grading for biochemistry parameters. Assessed grades were unknown, grade 0 [G0], grade 1 [G1] (mild), grade 2 [G2] (moderate), grade 3 [G3] (severe) and grade 4 [G4] (potentially life threatening), as compared to baseline at Day 0.

End point type	Primary

End point timeframe:

From Day 7 up to Day 30

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 Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
ALT, Unknown-Unknown [N=0;1]	0	1		
ALT, Unknown-G0 [N=0;1]	0	0		
ALT, Unknown-G1 [N=0;1]	0	0		
ALT, Unknown-G2 [N=0;1]	0	0		
ALT, Unknown-G3 [N=0;1]	0	0		
ALT, Unknown-G4 [N=0;1]	0	0		
ALT, G0-Unknown [N=49;50]	0	0		
ALT, G0-G0 [N=49;50]	48	49		
ALT, G0-G1 [N=49;50]	1	1		
ALT, G0-G2 [N=49;50]	0	0		
ALT, G0-G3 [N=49;50]	0	0		
ALT, G0-G4 [N=49;50]	0	0		
AST, G0-Unknown [N=48;51]	0	0		
AST, G0-G0 [N=48;51]	47	49		
AST, G0-G1 [N=48;51]	1	2		
AST, G0-G2 [N=48;51]	0	0		

AST, G0-G3 [N=48;51]	0	0		
AST, G0-G4 [N=48;51]	0	0		
AST, G1-Unknown [N=1;0]	0	0		
AST, G1-G0 [N=1;0]	0	0		
AST, G1-G1 [N=1;0]	1	0		
AST, G1-G2 [N=1;0]	0	0		
AST, G1-G3 [N=1;0]	0	0		
AST, G1-G4 [N=1;0]	0	0		
CRE, G0-Unknown [N=49;51]	0	0		
CRE, G0-G0 [N=49;51]	49	51		
CRE, G0-G1 [N=49;51]	0	0		
CRE, G0-G2 [N=49;51]	0	0		
CRE, G0-G3 [N=49;51]	0	0		
CRE, G0-G4 [N=49;51]	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with abnormal haematological laboratory parameter values by maximum grading

End point title	Number of subjects with abnormal haematological laboratory parameter values by maximum grading[2]

End point description:

Among haematological parameters tested were EOS, decreased Hgb and LYM graded by FDA toxicity grading for haematology parameters. Assessed grades were unknown, grade 0 [G0], grade 1 [G1] (mild), grade 2 [G2] (moderate), grade 3 [G3] (severe) and grade 4 [G4] (potentially life threatening), as compared to baseline at Day 0.

End point type	Primary

End point timeframe:

From Day 7 up to Day 30

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 Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
EOS, G0-Unknown [N=49;51]	0	0		
EOS, G0-G0 [N=49;51]	48	49		
EOS, G0-G1 [N=49;51]	1	2		
EOS, G0-G2 [N=49;51]	0	0		
EOS, G0-G3 [N=49;51]	0	0		
EOS, G0-G4 [N=49;51]	0	0		
Hgb/D, G0-Unknown [N=47;49]	0	0		
Hgb/D, G0-G0 [N=47;49]	45	46		
Hgb/D, G0-G1 [N=47;49]	2	3		
Hgb/D, G0-G2 [N=47;49]	0	0		

Hgb/D, G0-G3 [N=47;49]	0	0		
Hgb/D, G0-G4 [N=47;49]	0	0		
Hgb/D, G1-Unknown [N=2;1]	0	0		
Hgb/D, G1-G0 [N=2;1]	0	1		
Hgb/D, G1-G1 [N=2;1]	2	0		
Hgb/D, G1-G2 [N=2;1]	0	0		
Hgb/D, G1-G3 [N=2;1]	0	0		
Hgb/D, G1-G4 [N=2;1]	0	0		
Hgb/D, G4-Unknown [N=0;1]	0	0		
Hgb/D, G4-G0 [N=0;1]	0	0		
Hgb/D, G4-G1 [N=0;1]	0	0		
Hgb/D, G4-G2 [N=0;1]	0	0		
Hgb/D, G4-G3 [N=0;1]	0	0		
Hgb/D, G4-G4 [N=0;1]	0	1		
LYM, G0-Unknown [N=49;51]	0	0		
LYM, G0-G0 [N=49;51]	49	48		
LYM, G0-G1 [N=49;51]	0	2		
LYM, G0-G2 [N=49;51]	0	1		
LYM, G0-G3 [N=49;51]	0	0		
LYM, G0-G4 [N=49;51]	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with abnormal haematological laboratory parameter values by maximum grading

End point title	Number of subjects with abnormal haematological laboratory parameter values by maximum grading[3]

End point description:

Among haematological parameters tested were NEU, PLT, decreased WBC and increased WBC/I, graded by FDA toxicity grading for haematology parameters. Assessed grades were unknown, grade 0 [G0], grade 1 [G1] (mild), grade 2 [G2] (moderate), grade 3 [G3] (severe) and grade 4 [G4] (potentially life threatening), as compared to baseline at Day 0.

End point type	Primary

End point timeframe:

From Day 7 up to Day 30

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 Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
NEU, G0-Unknown [N=47;49]	0	0		
NEU, G0-G0 [N=47;49]	46	47		
NEU, G0-G1 [N=47;49]	1	2		
NEU, G0-G2 [N=47;49]	0	0		

NEU, G0-G3 [N=47;49]	0	0		
NEU, G0-G4 [N=47;49]	0	0		
NEU, G1-Unknown [N=2;2]	0	0		
NEU, G1-G0 [N=2;2]	0	2		
NEU, G1-G1 [N=2;2]	1	0		
NEU, G1-G2 [N=2;2]	1	0		
NEU, G1-G3 [N=2;2]	0	0		
NEU, G1-G4 [N=2;2]	0	0		
PLT, G0-Unknown [N=49;51]	0	0		
PLT, G0-G0 [N=49;51]	49	49		
PLT, G0-G1 [N=49;51]	0	2		
PLT, G0-G2 [N=49;51]	0	0		
PLT, G0-G3 [N=49;51]	0	0		
PLT, G0-G4 [N=49;51]	0	0		
WBC/D, G0-Unknown [N=49;51]	0	0		
WBC/D, G0-G0 [N=49;51]	49	50		
WBC/D, G0-G1 [N=49;51]	0	1		
WBC/D, G0-G2 [N=49;51]	0	0		
WBC/D, G0-G3 [N=49;51]	0	0		
WBC/D, G0-G4 [N=49;51]	0	0		
WBC/I, G0-Unknown [N=49;50]	0	0		
WBC/I, G0-G0 [N=49;50]	47	49		
WBC/I, G0-G1 [N=49;50]	2	1		
WBC/I, G0-G2 [N=49;50]	0	0		
WBC/I, G0-G3 [N=49;50]	0	0		
WBC/I, G0-G4 [N=49;50]	0	0		
WBC/I, G1-Unknown [N=0;1]	0	0		
WBC/I, G1-G0 [N=0;1]	0	1		
WBC/I, G1-G1 [N=0;1]	0	0		
WBC/I, G1-G2 [N=0;1]	0	0		
WBC/I, G1-G3 [N=0;1]	0	0		
WBC/I, G1-G4 [N=0;1]	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with haematology change from baseline by maximum grade

End point title	Number of subjects with haematology change from baseline by maximum grade[4]

End point description:

Assessed laboratory parameter changed from baseline was haemoglobin (Hgb). FDA grading for Hgb (change from baseline) was not applicable a baseline.

End point type	Primary

End point timeframe:

From Day 7 up to Day 30

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 Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
Hgb, G0	15	15		
Hgb, G1	34	35		
Hgb, G2	0	1		
Hgb, G3	0	0		
Hgb, G4	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with solicited local symptoms

End point title	Number of subjects with solicited local symptoms[5]

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = pain that prevented normal activity. Grade 3 redness/swelling = redness/swelling spreading beyond 100 millimetres (mm) of injection site. All solicited local symptoms are considered as related to the vaccination.

End point type	Primary

End point timeframe:

During a 7-day follow-up period (from Day 0 to Day 6) after 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 Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
Any Pain	27	46		
Grade 3 Pain	1	1		
Any Redness	0	1		
Grade 3 Redness	0	1		
Any Swelling	0	1		
Grade 3 Swelling	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[6]

End point description:

Assessed solicited general symptoms were fatigue, temperature (defined as oral temperature equal to or above [≥] 37.5 degrees Celsius [°C] for oral, axillary or tympanic route), gastrointestinal symptoms (gastro) including nausea, vomiting, diarrhoea and/or abdominal pain; and headache. Any = occurrence of the symptom regardless of intensity grade and relationship to the vaccination. Grade 3 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

End point timeframe:

During a 7-day follow-up period (from Day 0 to Day 6) after 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 Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
Any Fatigue	20	23		
Grade 3 Fatigue	4	1		
Related Fatigue	15	15		
Any Gastro.	14	14		
Grade 3 Gastro.	2	1		
Related Gastro.	8	9		
Any Headache	14	17		
Grade 3 Headache	3	1		
Related Headache	5	9		
Any temperature	2	2		
Grade 3 Temperature	0	0		
Related temperature	0	2		

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)[7]

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 out-side 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

End point timeframe:

During a 30-day follow-up period (from Day 0 to Day 29) after vaccination

Notes:

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

End point values	GSK3003891A Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
Any AE(S)	23	28		

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)[8]

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

End point timeframe:

From vaccination (Day 0) up to study end (Day 30)

Notes:

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

End point values	GSK3003891A Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
Any SAE(s)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Abnormal Biochemical Laboratory Values.

End point title	Number of subjects with Abnormal Biochemical Laboratory Values.[9]

End point description:

Among analysed biochemical parameters were alanine aminotransferase [ALT], aspartate aminotransferase [AST] and creatinine [CRE]. Biochemical value ranges assessed were below, within or

above, as compared to baseline at Day 0.

End point type	Primary

End point timeframe:

At Day 7

Notes:

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

End point values	GSK3003891A Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
ALT, Within-Bellow [N=49;51]	0	0		
ALT, Within-Within [N=49;51]	48	50		
ALT, Within-Above [N=49;51]	1	1		
AST, Within-Below [N=48;51]	0	0		
AST, Within-Within [N=48;51]	48	48		
AST, Within-Above [N=48;51]	0	3		
AST, Above-Below [N==1;0]	0	0		
AST, Above-Within [N=1;0]	0	0		
AST, Above-Above [N=1;0]	1	0		
CRE, Within-Bellow [N=49;51]	0	0		
CRE, Within-Within [N=49;51]	49	51		
CRE, Within-Above [N=49;51]	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Abnormal Biochemical Laboratory Values.

End point title	Number of subjects with Abnormal Biochemical Laboratory Values.[10]

End point description:

Among analysed biochemical parameters were alanine aminotransferase [ALT], aspartate aminotransferase [AST] and creatinine [CRE]. Biochemical value ranges assessed were below, within or above, as compared to baseline at Day 0.

End point type	Primary

End point timeframe:

At Day 30

Notes:

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

End point values	GSK3003891A Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	49	51		
Units: Subjects				
ALT, Within-Bellow [N=49;51]	0	0		
ALT, Within-Within [N=49;51]	48	51		
ALT, Within-Above [N=49;51]	1	0		
AST, Within-Below [N=48;51]	0	0		
AST, Within-Within [N=48;51]	47	51		
AST, Within-Above [N=48;51]	1	0		
AST, Above-Below [N=1;0]	0	0		
AST, Above-Within [N=1;0]	0	0		
AST, Above-Above [N=1;0]	1	0		
CRE, Within-Bellow [N=49;51]	0	0		
CRE, Within-Within [N=49;51]	49	51		
CRE, Within-Above [N=49;51]	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Abnormal Haematological Laboratory Values.

End point title	Number of subjects with Abnormal Haematological Laboratory Values.[11]

End point description:

Among analysed haematological parameters were eosinophils [EOS], haemoglobin [Hgb], leukocytes (white blood cells) [WBC], lymphocytes [LYM], neutrophils [NEU] and platelets [PLT]. Haematological value ranges assessed were below, within or above, as compared to baseline at Day 0. This outcome presents values for EOS, Hgb and WBC.

End point type	Primary

End point timeframe:

At Day 7

Notes:

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

End point values	GSK3003891A Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	50		
Units: Subjects				
EOS, Within-Bellow [N=48;47]	0	0		
EOS, Within-Within [N=48;47]	46	45		
EOS, Within-Above [N=48;47]	2	2		
EOS, Above-Below [N=1;4]	0	0		
EOS, Above-Within [N=1;4]	0	2		
EOS, Above-Above [N=1;4]	1	2		
Hgb, Below-Below [N=1;1]	0	1		
Hgb, Below-Within [N=1;1]	1	0		

Hgb, Below-Above [N=1;1]	0	0		
Hgb, Within-Bellow [N=48;50]	1	0		
Hgb, Within-Within [N=48;50]	47	50		
Hgb, Within-Above [N=48;50]	0	0		
WBC, Within-Bellow [N=48;50]	0	0		
WBC, Within-Within [N=48;50]	46	47		
WBC, Within-Above [N=48;50]	2	1		
WBC, Above-Below [N=1;3]	0	0		
WBC, Above-Within [N=1;3]	1	2		
WBC, Above-Above [N=1;3]	0	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Abnormal Haematological Laboratory Values.

End point title	Number of subjects with Abnormal Haematological Laboratory Values.[12]

End point description:

Among analysed haematological parameters were eosinophils [EOS], haemoglobin [Hgb], leukocytes (white blood cells) [WBC], lymphocytes [LYM], neutrophils [NEU] and platelets [PLT]. Haematological value ranges assessed were below, within or above, as compared to baseline at Day 0. This outcome presents values for EOS, Hgb and WBC.

End point type	Primary

End point timeframe:

At Day 30

Notes:

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

End point values	GSK3003891A Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	50		
Units: Subjects				
EOS, Within-Bellow [N=48;47]	0	0		
EOS, Within-Within [N=48;47]	41	44		
EOS, Within-Above [N=48;47]	7	3		
EOS, Above-Below [N=1;4]	0	0		
EOS, Above-Within [N=1;4]	0	3		
EOS, Above-Above [N=1;4]	1	1		
Hgb, Below-Below [N=1;1]	0	1		
Hgb, Below-Within [N=1;1]	1	0		
Hgb, Below-Above [N=1;1]	0	0		
Hgb, Within-Bellow [N=48;50]	0	0		
Hgb, Within-Within [N=48;50]	48	50		
Hgb, Within-Above [N=48;50]	0	0		
WBC, Within-Bellow [N=48;48]	0	1		
WBC, Within-Within [N=48;48]	47	45		

WBC, Within-Above [N=48;48]	1	2		
WBC, Above-Below [N=1;3]	0	0		
WBC, Above-Within [N=1;3]	1	3		
WBC, Above-Above [N=1;3]	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Abnormal Haematological Laboratory Values.

End point title	Number of subjects with Abnormal Haematological Laboratory Values.[13]

End point description:

Among analysed haematological parameters were eosinophils [EOS], haemoglobin [Hgb], leukocytes (white blood cells) [WBC], lymphocytes [LYM], neutrophils [NEU] and platelets [PLT]. Haematological value ranges assessed were below, within or above, as compared to baseline at Day 0. This outcome presents values for LYM, NEU and PLT

End point type	Primary

End point timeframe:

At Day 7

Notes:

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

End point values	GSK3003891A Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	50		
Units: Subjects				
LYM, Below-Below [N=0;2]	0	0		
LYM, Below-Within [N=0;2]	0	2		
LYM, Below-Above [N=0;2]	0	0		
LYM, Within-Bellow [N=46;48]	1	1		
LYM, Within-Within [N=46;48]	42	45		
LYM, Within-Above [N=46;48]	3	2		
LYM, Above-Below [N=3;1]	0	0		
LYM, Above-Within [N=3;1]	1	1		
LYM, Above-Above [N=3;1]	2	0		
NEU, Below-Below [N=1;0]	0	0		
NEU, Below-Within [N=1;0]	1	0		
NEU, Below-Above [N=1;0]	0	0		
NEU, Within-Bellow [N=47;48]	3	2		
NEU, Within-Within [N=47;48]	44	44		
NEU, Within-Above [N=47;48]	0	2		
NEU, Above-Below [N=1;3]	0	0		
NEU, Above-Within [N=1;3]	0	1		
NEU, Above-Above [N=1;3]	1	2		
PLT, Within-Bellow [N=48;50]	1	1		
PLT, Within-Within [N=48;50]	47	47		

PLT, Within-Above [N=48;50]	0	2		
PLT, Above-Below [N=1;1]	0	0		
PLT, Above-Within [N=1;1]	0	0		
PLT, Above-Above [N=1;1]	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Abnormal Haematological Laboratory Values.

End point title	Number of subjects with Abnormal Haematological Laboratory Values.[14]

End point description:

Among analysed haematological parameters were eosinophils [EOS], haemoglobin [Hgb], leukocytes (white blood cells) [WBC], lymphocytes [LYM], neutrophils [NEU] and platelets [PLT]. Haematological value ranges assessed were below, within or above, as compared to baseline at Day 0. This outcome presents values for LYM, NEU and PLT.

End point type	Primary

End point timeframe:

At Day 30

Notes:

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

End point values	GSK3003891A Group	Boostrix Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	48	50		
Units: Subjects				
LYM, Below-Below [N=0;2]	0	0		
LYM, Below-Within [N=0;2]	0	2		
LYM, Below-Above [N=0;2]	0	0		
LYM, Within-Bellow [N=46;48]	1	0		
LYM, Within-Within [N=46;48]	44	46		
LYM, Within-Above [N=46;48]	1	2		
LYM, Above-Below [N=3;1]	0	0		
LYM, Above-Within [N=3;1]	2	1		
LYM, Above-Above [N=3;1]	1	0		
NEU, Below-Below [N=1;0]	0	0		
NEU, Below-Within [N=1;0]	1	0		
NEU, Below-Above [N=1;0]	0	0		
NEU, Within-Bellow [N=47;48]	0	0		
NEU, Within-Within [N=47;48]	46	48		
NEU, Within-Above [N=47;48]	1	0		
NEU, Above-Below [N=1;3]	0	0		
NEU, Above-Within [N=1;3]	1	3		
NEU, Above-Above [N=1;3]	0	0		
PLT, Within-Bellow [N=48;50]	1	2		
PLT, Within-Within [N=48;50]	47	48		

PLT, Within-Above [N=48;50]	0	0		
PLT, Above-Below [N=1;1]	0	0		
PLT, Above-Within [N=1;1]	1	0		
PLT, Above-Above [N=1;1]	0	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Solicited and unsolicited AEs during the 30-Day follow-up period after vaccination; SAEs from Day 0 up to study end Day 30.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	GSK3003891A Group
Reporting group description:	
Healthy, non-pregnant women, aged 18-45 at the time of vaccination, were administered one dose of the investigational GSK3003891A vaccine, intramuscularly in the deltoid region of the arm, at Day 0	
Reporting group title	Boostrix Group
Reporting group description:	
Healthy, non-pregnant women, aged 18-45 at the time of vaccination, were administered one dose of the comparator Boostrix™ vaccine, intramuscularly in the deltoid region of the arm, at Day 0	

Serious adverse events	GSK3003891A Group	Boostrix Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 49 (0.00%)	0 / 51 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			

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

Non-serious adverse events	GSK3003891A Group	Boostrix Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	27 / 49 (55.10%)	46 / 51 (90.20%)	
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 49 (8.16%)	0 / 51 (0.00%)	
occurrences (all)	4	0	
Headache			
subjects affected / exposed	18 / 49 (36.73%)	25 / 51 (49.02%)	
occurrences (all)	18	25	
General disorders and administration site conditions			

Fatigue			
subjects affected / exposed	20 / 49 (40.82%)	24 / 51 (47.06%)	
occurrences (all)	20	24	
Pain			
subjects affected / exposed	27 / 49 (55.10%)	46 / 51 (90.20%)	
occurrences (all)	27	46	
Pyrexia			
subjects affected / exposed	2 / 49 (4.08%)	3 / 51 (5.88%)	
occurrences (all)	2	3	
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	14 / 49 (28.57%)	14 / 51 (27.45%)	
occurrences (all)	14	14	
Nausea			
subjects affected / exposed	1 / 49 (2.04%)	3 / 51 (5.88%)	
occurrences (all)	1	3	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 49 (4.08%)	4 / 51 (7.84%)	
occurrences (all)	2	4	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	1 / 49 (2.04%)	4 / 51 (7.84%)	
occurrences (all)	1	4	
Pharyngitis			
subjects affected / exposed	3 / 49 (6.12%)	1 / 51 (1.96%)	
occurrences (all)	3	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported