Clinical trial results:
A Phase II, randomised, observer-blind, controlled, multi-country study to rank different formulations of GSK Biologicals' investigational RSV vaccine (GSK3003891A), based on immunogenicity, reactogenicity and safety, when administered to healthy women, aged 18-45 years.

Summary

EudraCT number	2016-001135-12
Trial protocol	DE EE BE FR
Global end of trial date	05 February 2018

Results information

Result version number	v1 (current)
This version publication date	14 September 2018
First version publication date	14 September 2018

Trial information

Trial identification

Sponsor protocol code	204812

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02956837
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, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, 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	05 February 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 February 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To rank different formulations of the investigational GSK3003891A respiratory syncytial virus (RSV) vaccine based on safety/reactogenicity and immunogenicity data up to 1 month post-vaccination (Day 30).

Protection of trial subjects:

Study procedures related to the protection of trial subjects included close observation of the subject for at least 30 minutes following study vaccination, with appropriate medical treatment readily available in case of anaphylaxis.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 November 2016
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	Belgium: 100
Country: Number of subjects enrolled	Estonia: 100
Country: Number of subjects enrolled	France: 97
Country: Number of subjects enrolled	Germany: 109
Worldwide total number of subjects	406
EEA total number of subjects	406

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)	406

From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study started enrolling subjects in 2016 and concluded in 2018.

Pre-assignment

Screening details:

Out of 406 subjects initially enrolled in the study, 6 subjects had numbers allocated but did not receive any study vaccine dose, hence only 400 subjects were included in the Total Vaccinated Cohort.

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, Data analyst, Assessor

Blinding implementation details:

Observer-Blinding in Epoch 001 (up to Day 90). In an observer-blind study, the subject and the site and sponsor personnel involved in the clinical evaluation of the subjects are blinded while other study personnel may be aware of the treatment assignment.
Single Blinding in Epoch 002 (up to Day 360). In a single-blind study, the investigator and/or his staff are aware of the treatment assignment but the subject is not.

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK3003891A vaccine formulation 1 Group

Arm description:

Subjects in this group received a single 30 micrograms (µg) dose injection of the investigational GSK3003891A vaccine at Day 0.

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

Dosage and administration details:

Single 30 µg dose administered intramuscularly at Day 0 in the deltoid region of the non-dominant arm.

Arm title	GSK3003891A vaccine formulation 2 Group

Arm description:

Subjects in this group received a single 60 µg dose injection of the investigational GSK3003891A vaccine at Day 0.

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

Dosage and administration details:

Single 60 µg dose administered intramuscularly at Day 0 in the deltoid region of the non-dominant arm.

Arm title	GSK3003891A vaccine formulation 3 Group

Arm description:

Subjects in this group received a single 120 µg dose injection of the investigational GSK3003891A vaccine at Day 0.

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

Dosage and administration details:

Single 120 µg dose administered intramuscularly at Day 0 in the deltoid region of the non-dominant arm.

Arm title	Control Group

Arm description:

Subjects in this group received a single placebo injection at Day 0.

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

Dosage and administration details:

Single dose administered intramuscularly at Day 0 in the deltoid region of the non-dominant arm.

Number of subjects in period 1[1]	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group
Started	100	99	99
Completed	100	96	97
Not completed	0	3	2
Consent withdrawn by subject	-	1	-
Serious Adverse Events	-	1	-
Lost to follow-up	-	1	2

Number of subjects in period 1[1]	Control Group
Started	102
Completed	99
Not completed	3
Consent withdrawn by subject	3
Serious Adverse Events	-
Lost to follow-up	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Out of 406 subjects initially enrolled in the study, 6 subjects had numbers allocated but did not receive any study vaccine dose, hence only 400 subjects were included in the Total Vaccinated Cohort.

Baseline characteristics

Reporting groups	
Reporting group title	GSK3003891A vaccine formulation 1 Group
Reporting group description:	
Subjects in this group received a single 30 micrograms (µg) dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	GSK3003891A vaccine formulation 2 Group
Reporting group description:	
Subjects in this group received a single 60 µg dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	GSK3003891A vaccine formulation 3 Group
Reporting group description:	
Subjects in this group received a single 120 µg dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	Control Group
Reporting group description:	
Subjects in this group received a single placebo injection at Day 0.	

Reporting group values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group
Number of subjects	100	99	99
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	30.2	29.1	29.6
standard deviation	± 6.7	± 7.2	± 7.1
Gender categorical Units: Subjects			
Female	100	99	99
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
African Heritage/African American	1	0	2
Asian - Central/South Asian Heritage	1	1	0
Asian - East Asian Heritage	0	0	1
Asian - South East Asian Heritage	0	0	0
White - Arabic/North African Heritage	0	1	2
White - Caucasian/European Heritage	96	97	93
Unspecified	2	0	1

Reporting group values	Control Group	Total	
Number of subjects	102	400	

Age categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	29.9		
standard deviation	± 6.9	-	
Gender categorical Units: Subjects			
Female	102	400	
Male	0	0	
Race/Ethnicity, Customized Units: Subjects			
African Heritage/African American	1	4	
Asian - Central/South Asian Heritage	0	2	
Asian - East Asian Heritage	0	1	
Asian - South East Asian Heritage	1	1	
White - Arabic/North African Heritage	1	4	
White - Caucasian/European Heritage	98	384	
Unspecified	1	4	

End points

End points reporting groups

Reporting group title	GSK3003891A vaccine formulation 1 Group
Reporting group description:	
Subjects in this group received a single 30 micrograms (µg) dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	GSK3003891A vaccine formulation 2 Group
Reporting group description:	
Subjects in this group received a single 60 µg dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	GSK3003891A vaccine formulation 3 Group
Reporting group description:	
Subjects in this group received a single 120 µg dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	Control Group
Reporting group description:	
Subjects in this group received a single placebo injection at Day 0.	

Primary: Number of subjects with any Grade 2 and Grade 3 general Adverse Events (AEs) - solicited and unsolicited

End point title	Number of subjects with any Grade 2 and Grade 3 general Adverse Events (AEs) - solicited and unsolicited[1]
End point description:	
Assessed solicited general AEs were fatigue, gastrointestinal symptoms [nausea, vomiting, diarrhea and/or abdominal pain], fever and headache. 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.Grade 2 symptoms = occurrence of symptoms discomforting enough to interfere with daily activities. Grade 3 symptoms = symptoms that prevented normal activities. This primary objective focused only on subjects from the investigational GSK3003891A vaccine groups (GSK3003891A vaccine formulation 1 Group, GSK3003891A vaccine formulation 2 Group and GSK3003891A vaccine formulation 3 Group).	
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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.	

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	99	99	102
Units: Participants				
Participants	32	30	24	27

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with Grade 2 and Grade 3 fever

End point title	Number of subjects with Grade 2 and Grade 3 fever[2]

End point description:

Grade 2 Fever was defined as oral temperature above (>) 38.5 degrees Celsius (°C) to less than or equal to (≤) 39.5°C. Grade 3 Fever was defined as oral temperature > 39.5°C. This primary objective focused only on subjects from the investigational GSK3003891A vaccine groups (GSK3003891A vaccine formulation 1 Group, GSK3003891A vaccine formulation 2 Group and GSK3003891A vaccine formulation 3 Group).

End point type	Primary

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

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	98	99	102
Units: Participants				
Grade 2 Fever	0	2	1	0
Grade 3 Fever	0	1	0	0

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with related serious adverse events

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. Related SAEs = SAEs assessed by the investigator as related to the vaccination. This primary objective focused only on subjects from the investigational GSK3003891A vaccine groups (GSK3003891A vaccine formulation 1 Group, GSK3003891A vaccine formulation 2 Group and GSK3003891A vaccine formulation 3 Group).

End point type	Primary

End point timeframe:

During the 7-day (Days 0-6) 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 analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	99	99	102
Units: Participants				
Participants	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Neutralizing antibody titers against RSV-A subtype

End point title	Neutralizing antibody titers against RSV-A subtype[4]

End point description:

RSV-A is one of the two antigenically distinct subgroups of the Respiratory Synctial Virus (RSV). Antibody titers were determined by neutralization assay and presented as geometric mean titers (GMTs), for a seropositivity cut-off value greater than or equal to (≥) 8 ED60 (Estimated Dilution 60). This primary objective focused only on subjects from the investigational GSK3003891A vaccine groups (GSK3003891A vaccine formulation 1 Group, GSK3003891A vaccine formulation 2 Group and GSK3003891A vaccine formulation 3 Group).

End point type	Primary

End point timeframe:

At Day 0

Notes:

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

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	95	98	100
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-RSV.A	228.8 (193.1 to 271.0)	249.5 (213.9 to 290.9)	285.7 (244.5 to 333.9)	247.1 (211.2 to 289.1)

Statistical analyses

No statistical analyses for this end point

Primary: Neutralizing antibody titers against RSV-A subtype

End point title	Neutralizing antibody titers against RSV-A subtype[5]

End point description:

RSV-A is one of the two antigenically distinct subgroups of the Respiratory Synctial Virus (RSV). Antibody titers were determined by neutralization assay and presented as geometric mean titers (GMTs), for a seropositivity cut-off value ≥ 8 ED60 (Estimated Dilution 60). This primary objective focused only on subjects from the investigational GSK3003891A vaccine groups (GSK3003891A vaccine formulation 1 Group, GSK3003891A vaccine formulation 2 Group and GSK3003891A vaccine formulation 3 Group).

End point type	Primary

End point timeframe:

At Day 30

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.

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	94	98	100
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-RSV.A	858.2 (724.7 to 1016.3)	1114.8 (971.9 to 1278.8)	1245.5 (1070.3 to 1449.2)	271.6 (228.0 to 323.5)

Statistical analyses

No statistical analyses for this end point

Primary: Palivizumab competing antibody (PCA) concentrations

End point title	Palivizumab competing antibody (PCA) concentrations[6]

End point description:

PCA concentrations were determined by Enzyme-Linked Immunosorbent Assay (ELISA), presented as geometric mean concentrations (GMCs) and expressed in micrograms per milliliter (µg/mL), for a seropositivity cut-off ≥ 9.6 µg/mL. This primary objective focused only on subjects from the investigational GSK3003891A vaccine groups (GSK3003891A vaccine formulation 1 Group, GSK3003891A vaccine formulation 2 Group and GSK3003891A vaccine formulation 3 Group).

End point type	Primary

End point timeframe:

At Day 0

Notes:

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

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	94	96	100
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PCA	5.7 (5.3 to 6.2)	5.6 (5.2 to 6.1)	5.8 (5.3 to 6.3)	6.0 (5.5 to 6.6)

Statistical analyses

No statistical analyses for this end point

Primary: Pavilizumab competing antibody (PCA) concentrations

End point title	Pavilizumab competing antibody (PCA) concentrations[7]

End point description:

PCA concentrations were determined by Enzyme-Linked Immunosorbent Assay (ELISA), presented as geometric mean concentrations (GMCs) and expressed in micrograms per milliliter (µg/mL), for a seropositivity cut-off ≥ 9.6 µg/mL. This primary objective focused only on subjects from the investigational GSK3003891A vaccine groups (GSK3003891A vaccine formulation 1 Group, GSK3003891A vaccine formulation 2 Group and GSK3003891A vaccine formulation 3 Group).

End point type	Primary

End point timeframe:

At Day 30

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.

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	94	98	100
Units: µg/mL				
geometric mean (confidence interval 95%)				
Anti-PCA	66.8 (59.0 to 75.8)	81.2 (72.5 to 90.9)	83.7 (73.5 to 95.5)	6.1 (5.5 to 6.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, Grade 2, Grade 3 and medically attended solicited local AEs

End point title	Number of subjects with any, Grade 2, Grade 3 and medically attended solicited local AEs

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 2 pain = painful when limb was moved and that interfered with every day activities.Grade 3 pain = significant pain at rest, pain that prevented normal every day activity. Grade 2 redness/swelling = redness/swelling spreading beyond (>) 50 millimeters (mm) and up to (and including) 100 mm of injection site.Grade 3 redness/swelling = redness/swelling > 100 mm of injection site. Medically attended symptoms = occurrence of symptoms that required medical advice.

End point type	Secondary

End point timeframe:

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

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	98	99	102
Units: Participants				
Any Pain	52	52	51	11
Grade 2 Pain	5	5	10	1
Grade 3 Pain	1	0	1	0
Medically-attended Pain	0	0	0	0
Any Redness (mm)	6	10	8	1
Grade 2 Redness (mm)	2	2	1	0
Grade 3 Redness	0	0	0	0
Medically-attended Redness (mm)	0	0	0	0
Any Swelling (mm)	4	6	7	0
Grade 2 Swelling (mm)	1	0	0	0
Grade 3 Swelling (mm)	0	1	0	0
Medically-attended Swelling (mm)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, Grade 2, Grade 3, related and medically attended solicited general AEs

End point title	Number of subjects with any, Grade 2, Grade 3, related and medically attended solicited general AEs

End point description:

Assessed solicited general symptoms were fatigue, gastrointestinal symptoms (which include nausea, vomiting, diarrhoea and/or abdominal pain), headache, fever [defined as oral temperature equal to or above (≥) 37.5 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 2 symptoms = occurrence of symptoms discomforting enough to interfere with daily activities. Grade 3 symptoms = symptoms that prevented normal activities.Related = symptom assessed by the investigator as related to the vaccination. Medically attended symptom = occurrence of symptom that required medical advice.

End point type	Secondary

End point timeframe:

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

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	98	99	102
Units: Participants				
Any Fatigue	47	43	45	42
Grade 2 Fatigue	9	14	8	12
Grade 3 Fatigue	3	3	2	1
Related Fatigue	37	29	36	33
Medically-attended Fatigue	0	1	1	0
Any Gastrointestinal symptoms	20	23	14	11
Grade 2 Gastrointestinal symptoms	4	3	1	1
Grade 3 Gastrointestinal symptoms	1	2	0	1
Related Gastrointestinal symptoms	13	17	10	7
Medically-attended Gastrointestinal symptoms	0	0	0	0
Any Headache	47	42	41	37
Grade 2 Headache	11	11	12	10
Grade 3 Headache	3	2	1	3
Related Headache	30	27	33	29
Medically-attended Headache	0	1	1	0
Any Temperature/(Oral) (°C)	8	8	6	4
Related Temperature/(Oral) (°C)	5	1	6	2
Medically-attended Temperature/(Oral) (°C)	0	3	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any unsolicited AEs

End point title	Number of subjects with any unsolicited AEs

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	Secondary

End point timeframe:

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

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	99	99	102
Units: Participants				
Participants	55	52	46	49

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any SAEs

End point title	Number of subjects with any 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:

From Day 0 up to study end, at Day 360

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	99	99	102
Units: Participants				
Participants	1	3	2	2

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any biochemical and hematological laboratory abnormalities

End point title	Number of subjects with any biochemical and hematological laboratory abnormalities

End point description:

Biochemical parameters assessed included alanine aminotransferase [ALT], aspartate aminotransferase [AST] and creatinine. Hematological parameters assessed included eosinophils, hemoglobin level, lymphocytes, neutrophils, platelet count and White Blood Cells [WBC]. Abnormal laboratory values at Day 7 were Below, Within and Above normal ranges, as compared to the baseline status of the same parameter, at Day 0 (Unknown, Below, Within and Above normal ranges) [e.g. ALT Below - Within = ALT with below normal value at baseline and within normal values at Day 7].

End point type	Secondary

End point timeframe:
At Day 7

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	98	99	102
Units: Participants				
ALT, Below-Below [N=0;0;0;0]	0	0	0	0
ALT, Below-Within [N=0;0;0;0]	0	0	0	0
ALT, Below-Above [N=0;0;0;0]	0	0	0	0
ALT, Within-Below [N=99;97;99;102]	0	0	0	0
ALT, Within-Within [N=99;97;99;102]	99	97	99	102
ALT, Within-Above [N=99;97;99;102]	0	0	0	0
ALT, Above-Below [N=1;1;0;0]	0	0	0	0
ALT, Above-Within [N=1;1;0;0]	1	1	0	0
ALT, Above-Above [N=1;1;0;0]	0	0	0	0
AST, Below-Below [N=0;0;0;0]	0	0	0	0
AST, Below-Within [N=0;0;0;0]	0	0	0	0
AST, Below-Above [N=0;0;0;0]	0	0	0	0
AST, Within-Below [N=99;97;99;100]	0	0	0	0
AST, Within-Within [N=99;97;99;100]	99	97	98	100
AST, Within-Above [N=99;97;99;100]	0	0	1	0
AST, Above-Below [N=1;1;0;1]	0	0	0	0
AST, Above-Within [N=1;1;0;1]	1	1	0	1
AST, Above-Above [N=1;1;0;1]	0	0	0	0
Creatinine, Below-Below [N=6;5;2;2]	2	3	2	0
Creatinine, Below-Within [N=6;5;2;2]	4	2	0	2
Creatinine, Below-Above [N=6;5;2;2]	0	0	0	0
Creatinine, Within-Below [N=93;92;97;99]	1	2	4	0
Creatinine, Within-Within [N=93;92;97;99]	92	90	93	99
Creatinine, Within-Above [N=93;92;97;99]	0	0	0	0
Creatinine, Above-Below [N=1;1;0;1]	0	0	0	0
Creatinine, Above-Within [N=1;1;0;1]	0	1	0	0
Creatinine, Above-Above [N=1;1;0;1]	1	0	0	1
Eosinophils, Unknown-Below [N=1;1;1;1]	0	0	0	0
Eosinophils, Unknown-Within [N=1;1;1;1]	1	1	1	1
Eosinophils, Unknown-Above [N=1;1;1;1]	0	0	0	0
Eosinophils, Below-Below [N=12;8;10;8]	5	5	3	6
Eosinophils, Below-Within [N=12;8;10;8]	7	3	7	2
Eosinophils, Below-Above [N=12;8;10;8]	0	0	0	0

Eosinophils, Within-Below [N=81;86;83;89]	3	2	4	5
Eosinophils, Within-Within [N=81;86;83;89]	77	84	79	81
Eosinophils, Within-Above [N=81;86;83;89]	1	0	0	3
Eosinophils, Above-Below [N=2;0;0;0]	0	0	0	0
Eosinophils, Above-Within [N=2;0;0;0]	1	0	0	0
Eosinophils, Above-Above [N=2;0;0;0]	1	0	0	0
Hemoglobin, Unknown-Below [N=1;0;0;1]	0	0	0	0
Hemoglobin, Unknown-Within [N=1;0;0;1]	1	0	0	1
Hemoglobin, Unknown-Above [N=1;0;0;1]	0	0	0	0
Hemoglobin, Below-Below [N=20;11;8;11]	12	7	7	7
Hemoglobin, Below-Within [N=20;11;8;11]	8	4	1	4
Hemoglobin, Below-Above [N=20;11;8;11]	0	0	0	0
Hemoglobin, Within-Below [N=79;85;91;90]	4	1	7	2
Hemoglobin, Within-Within [N=79;85;91;90]	74	84	84	88
Hemoglobin, Within-Above [N=79;85;91;90]	1	0	0	0
Hemoglobin, Above-Below [N=0;2;0;0]	0	0	0	0
Hemoglobin, Above-Within [N=0;2;0;0]	0	1	0	0
Hemoglobin, Above-Above [N=0;2;0;0]	0	1	0	0
Lymphocytes, Unknown-Below [N=1;1;1;1]	0	0	0	0
Lymphocytes, Unknown-Within [N=1;1;1;1]	1	1	1	1
Lymphocytes, Unknown-Above [N=1;1;1;1]	0	0	0	0
Lymphocytes, Below-Below [N=1;0;0;1]	0	0	0	1
Lymphocytes, Below-Within [N=1;0;0;1]	1	0	0	0
Lymphocytes, Below-Above [N=1;0;0;1]	0	0	0	0
Lymphocytes, Within-Below [N=93;93;93;96]	1	0	0	0
Lymphocytes, Within-Within [N=93;93;93;96]	92	93	92	94
Lymphocytes, Within-Above [N=93;93;93;96]	0	0	1	2
Lymphocytes, Above-Below [N=1;1;0;0]	0	0	0	0
Lymphocytes, Above-Within [N=1;1;0;0]	1	1	0	0
Lymphocytes, Above-Above [N=1;1;0;0]	0	0	0	0
Neutrophils, Unknown-Below [N=1;1;1;1]	0	0	1	0
Neutrophils, Unknown-Within [N=1;1;1;1]	1	1	0	1
Neutrophils, Unknown-Above [N=1;1;1;1]	0	0	0	0
Neutrophils, Below-Below [N=4;1;0;3]	2	0	0	1

Neutrophils, Below-Within [N=4;1;0;3]	2	1	0	2
Neutrophils, Below-Above [N=4;1;0;3]	0	0	0	0
Neutrophils, Within-Below [N=91;89;90;93]	2	6	4	8
Neutrophils, Within-Within [N=91;89;90;93]	88	81	86	82
Neutrophils, Within-Above [N=91;89;90;93]	1	2	0	3
Neutrophils, Above-Below [N=0;4;3;1]	0	0	0	0
Neutrophils, Above-Within [N=0;4;3;1]	0	4	3	1
Neutrophils, Above-Above [N=0;4;3;1]	0	0	0	0
Platelet count, Unknown-Below [N=2;2;0;1]	0	0	0	0
Platelet count, Unknown-Within [N=2;2;0;1]	2	2	0	1
Platelet count, Unknown-Above [N=2;2;0;1]	0	0	0	0
Platelet count, Below-Below [N=0;0;0;0]	0	0	0	0
Platelet count, Below-Within [N=0;0;0;0]	0	0	0	0
Platelet count, Below-Above [N=0;0;0;0]	0	0	0	0
Platelet count, Within-Below [N=95;96;99;100]	1	1	0	0
Platelet count, Within-Within [N=95;96;99;100]	93	95	99	100
Platelet count, Within-Above [N=95;96;99;100]	1	0	0	0
Platelet count, Above-Below [N=1;0;0;1]	0	0	0	0
Platelet count, Above-Within [N=1;0;0;1]	1	0	0	1
Platelet count, Above-Above [N=1;0;0;1]	0	0	0	0
WBC, Unknown-Below [N=1;0;0;1]	0	0	0	0
WBC, Unknown-Within [N=1;0;0;1]	1	0	0	1
WBC, Unknown-Above [N=1;0;0;1]	0	0	0	0
WBC, Below-Below [N=3;0;1;5]	2	0	0	2
WBC, Below-Within [N=3;0;1;5]	1	0	1	3
WBC, Below-Above [N=3;0;1;5]	0	0	0	0
WBC, Within-Below [N=95;93;94;94]	4	4	1	4
WBC, Within-Within [N=95;93;94;94]	90	87	92	87
WBC, Within-Above [N=95;93;94;94]	1	2	1	3
WBC, Above-Below [N=0;4;3;1]	0	0	0	0
WBC, Above-Within [N=0;4;3;1]	0	3	3	1
WBC, Above-Above [N=0;4;3;1]	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any biochemical and hematological laboratory abnormalities

End point title	Number of subjects with any biochemical and hematological laboratory abnormalities

End point description:

Biochemical parameters assessed included alanine aminotransferase [ALT], aspartate aminotransferase [AST] and creatinine. Hematological parameters assessed included eosinophils, hemoglobin level, lymphocytes, neutrophils, platelet count and White Blood Cells [WBC]. Abnormal laboratory values at Day 30 were Below, Within and Above normal ranges, as compared to the baseline values of the same parameter, at Day 0 (Unknown, Below, Within and Above normal ranges) [e.g. ALT Below - Within = ALT with below normal value at baseline and within normal values at Day 30].

End point type	Secondary

End point timeframe:

At Day 30

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99	98	99	102
Units: Participants				
ALT, Below-Below [N=0;0;0;0]	0	0	0	0
ALT, Below-Within [N=0;0;0;0]	0	0	0	0
ALT, Below-Above [N=0;0;0;0]	0	0	0	0
ALT, Within-Below [N=96;97;99;102]	0	0	0	0
ALT, Within-Within [N=96;97;99;102]	93	97	96	101
ALT, Within-Above [N=96;97;99;102]	3	0	3	1
ALT, Above-Below [N=1;1;0;0]	0	0	0	0
ALT, Above-Within [N=1;1;0;0]	1	0	0	0
ALT, Above-Above [N=1;1;0;0]	0	1	0	0
AST, Below-Below [N=0;0;0;0]	0	0	0	0
AST, Below-Within [N=0;0;0;0]	0	0	0	0
AST, Below-Above [N=0;0;0;0]	0	0	0	0
AST, Within-Below [N=96;97;99;101]	0	0	0	0
AST, Within-Within [N=96;97;99;101]	94	97	97	100
AST, Within-Above [N=96;97;99;101]	2	0	2	1
AST, Above-Below [N=1;1;0;1]	0	0	0	0
AST, Above-Within [N=1;1;0;1]	1	0	0	1
AST, Above-Above [N=1;1;0;1]	0	1	0	0
Creatinine, Below-Below [N=6;5;2;2]	1	2	2	2
Creatinine, Below-Within [N=6;5;2;2]	5	3	0	0
Creatinine, Below-Above [N=6;5;2;2]	0	0	0	0
Creatinine, Within-Below [N=90;92;97;99]	1	0	3	2
Creatinine, Within-Within [N=90;92;97;99]	89	91	93	97
Creatinine, Within-Above [N=90;92;97;99]	0	1	1	0
Creatinine, Above-Below [N=1;1;0;1]	0	0	0	0
Creatinine, Above-Within [N=1;1;0;1]	1	0	0	1
Creatinine, Above-Above [N=1;1;0;1]	0	1	0	0
Eosinophils, Unknown-Below [N=1;1;1;1]	0	1	0	0

Eosinophils, Unknown-Within [N=1;1;1;1]	1	0	1	1
Eosinophils, Unknown-Above [N=1;1;1;1]	0	0	0	0
Eosinophils, Below-Below [N=12;8;11;8]	5	4	4	4
Eosinophils, Below-Within [N=12;8;11;8]	7	4	7	4
Eosinophils, Below-Above [N=12;8;11;8]	0	0	0	0
Eosinophils, Within-Below [N=84;88;86;90]	3	6	8	7
Eosinophils, Within-Within [N=84;88;86;90]	80	82	75	83
Eosinophils, Within-Above [N=84;88;86;90]	1	0	3	0
Eosinophils, Above-Below [N=2;0;0;0]	0	0	0	0
Eosinophils, Above-Within [N=2;0;0;0]	1	0	0	0
Eosinophils, Above-Above [N=2;0;0;0]	1	0	0	0
Hemoglobin, Unknown-Below [N=1;0;0;1]	0	0	0	0
Hemoglobin, Unknown-Within [N=1;0;0;1]	1	0	0	1
Hemoglobin, Unknown-Above [N=1;0;0;1]	0	0	0	0
Hemoglobin, Below-Below [N=20;11;8;11]	13	6	6	7
Hemoglobin, Below-Within [N=20;11;8;11]	7	5	2	4
Hemoglobin, Below-Above [N=20;11;8;11]	0	0	0	0
Hemoglobin, Within-Below [N=78;84;91;90]	2	4	5	3
Hemoglobin, Within-Within [N=78;84;91;90]	76	79	86	87
Hemoglobin, Within-Above [N=78;84;91;90]	0	1	0	0
Hemoglobin, Above-Below [N=0;2;0;0]	0	0	0	0
Hemoglobin, Above-Within [N=0;2;0;0]	0	1	0	0
Hemoglobin, Above-Above [N=0;2;0;0]	0	1	0	0
Lymphocytes, Unknown-Below [N=1;1;1;1]	0	0	0	0
Lymphocytes, Unknown-Within [N=1;1;1;1]	1	1	1	1
Lymphocytes, Unknown-Above [N=1;1;1;1]	0	0	0	0
Lymphocytes, Below-Below [N=1;0;0;1]	0	0	0	1
Lymphocytes, Below-Within [N=1;0;0;1]	1	0	0	0
Lymphocytes, Below-Above [N=1;0;0;1]	0	0	0	0
Lymphocytes, Within-Below [N=96;95;97;97]	1	0	0	0
Lymphocytes, Within-Within [N=96;95;97;97]	94	94	97	95
Lymphocytes, Within-Above [N=96;95;97;97]	1	1	0	2
Lymphocytes, Above-Below [N=1;1;0;0]	0	0	0	0
Lymphocytes, Above-Within [N=1;1;0;0]	1	1	0	0

Lymphocytes, Above-Above [N=1;1;0;0]	0	0	0	0
Neutrophils, Unknown-Below [N=1;1;1;1]	0	0	0	0
Neutrophils, Unknown-Within [N=1;1;1;1]	1	1	1	1
Neutrophils, Unknown-Above [N=1;1;1;1]	0	0	0	0
Neutrophils, Below-Below [N=4;1;0;3]	1	0	0	0
Neutrophils, Below-Within [N=4;1;0;3]	3	1	0	3
Neutrophils, Below-Above [N=4;1;0;3]	0	0	0	0
Neutrophils, Within-Below [N=94;91;94;94]	4	1	1	3
Neutrophils, Within-Within [N=94;91;94;94]	88	88	92	88
Neutrophils, Within-Above [N=94;91;94;94]	2	2	1	3
Neutrophils, Above-Below [N=0;4;3;1]	0	0	0	0
Neutrophils, Above-Within [N=0;4;3;1]	0	3	3	1
Neutrophils, Above-Above [N=0;4;3;1]	0	1	0	0
Platelet count, Unknown-Below [N=2;2;0;1]	0	0	0	0
Platelet count, Unknown-Within [N=2;2;0;1]	2	2	0	1
Platelet count, Unknown-Above [N=2;2;0;1]	0	0	0	0
Platelet count, Below-Below [N=0;0;0;0]	0	0	0	0
Platelet count, Below-Within [N=0;0;0;0]	0	0	0	0
Platelet count, Below-Above [N=0;0;0;0]	0	0	0	0
Platelet count, Within-Below [N=94;95;99;100]	0	0	0	0
Platelet count, Within-Within [N=94;95;99;100]	92	94	99	99
Platelet count, Within-Above [N=94;95;99;100]	2	1	0	1
Platelet count, Above-Below [N=1;0;0;1]	0	0	0	0
Platelet count, Above-Within [N=1;0;0;1]	1	0	0	1
Platelet count, Above-Above [N=1;0;0;1]	0	0	0	0
WBC, Unknown-Below [N=1;0;0;1]	0	0	0	0
WBC, Unknown-Within [N=1;0;0;1]	1	0	0	1
WBC, Unknown-Above [N=1;0;0;1]	0	0	0	0
WBC, Below-Below [N=3;0;2;4]	2	0	1	0
WBC, Below-Within [N=3;0;2;4]	1	0	1	4
WBC, Below-Above [N=3;0;2;4]	0	0	0	0
WBC, Within-Below [N=95;93;94;95]	3	1	3	0
WBC, Within-Within [N=95;93;94;95]	90	89	90	90
WBC, Within-Above [N=95;93;94;95]	2	3	1	5
WBC, Above-Below [N=0;4;3;1]	0	0	0	0
WBC, Above-Within [N=0;4;3;1]	0	2	2	1
WBC, Above-Above [N=0;4;3;1]	0	2	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any biochemical and hematological laboratory abnormalities

End point title	Number of subjects with any biochemical and hematological laboratory abnormalities

End point description:

Biochemical parameters assessed included alanine aminotransferase [ALT], aspartate aminotransferase [AST] and creatinine. Hematological parameters assessed included eosinophils, hemoglobin level, lymphocytes, neutrophils, platelet count and White Blood Cells [WBC]. Abnormal laboratory values at Day 60 were Below, Within and Above normal ranges, as compared to the baseline status of the same parameter, at Day 0 (Unknown, Below, Within and Above normal ranges) [e.g. ALT Below - Within = ALT with below normal value at baseline and within normal values at Day 60].

End point type	Secondary

End point timeframe:

At Day 60

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	96	98	101
Units: Participants				
ALT, Below-Below [N=0;0;0;0]	0	0	0	0
ALT, Below-Within [N=0;0;0;0]	0	0	0	0
ALT, Below-Above [N=0;0;0;0]	0	0	0	0
ALT, Within-Below [N=98;95;98;101]	0	0	0	0
ALT, Within-Within [N=98;95;98;101]	98	95	98	101
ALT, Within-Above [N=98;95;98;101]	0	0	0	0
ALT, Above-Below [N=1;1;0;0]	0	0	0	0
ALT, Above-Within [N=1;1;0;0]	1	1	0	0
ALT, Above-Above [N=1;1;0;0]	0	0	0	0
AST, Below-Below [N=0;0;0;0]	0	0	0	0
AST, Below-Within [N=0;0;0;0]	0	0	0	0
AST, Below-Above [N=0;0;0;0]	0	0	0	0
AST, Within-Below [N=98;95;98;100]	0	0	0	0
AST, Within-Within [N=98;95;98;100]	98	95	97	100
AST, Within-Above [N=98;95;98;100]	0	0	1	0
AST, Above-Below [N=1;1;0;1]	0	0	0	0
AST, Above-Within [N=1;1;0;1]	1	1	0	1
AST, Above-Above [N=1;1;0;1]	0	0	0	0
Creatinine, Below-Below [N=6;5;2;2]	0	3	2	2

Creatinine, Below-Within [N=6;5;2;2]	6	2	0	0
Creatinine, Below-Above [N=6;5;2;2]	0	0	0	0
Creatinine, Within-Below [N=92;90;96;98]	2	3	3	6
Creatinine, Within-Within [N=92;90;96;98]	89	87	93	91
Creatinine, Within-Above [N=92;90;96;98]	1	0	0	1
Creatinine, Above-Below [N=1;1;0;1]	0	0	0	0
Creatinine, Above-Within [N=1;1;0;1]	1	1	0	1
Creatinine, Above-Above [N=1;1;0;1]	0	0	0	0
Eosinophils, Unknown-Below [N=1;0;1;1]	0	0	0	0
Eosinophils, Unknown-Within [N=1;0;1;1]	1	0	1	1
Eosinophils, Unknown-Above [N=1;0;1;1]	0	0	0	0
Eosinophils, Below-Below [N=12;8;10;9]	5	2	4	5
Eosinophils, Below-Within [N=12;8;10;9]	7	6	6	4
Eosinophils, Below-Above [N=12;8;10;9]	0	0	0	0
Eosinophils, Within-Below [N=85;87;85;91]	6	4	5	7
Eosinophils, Within-Within [N=85;87;85;91]	77	82	77	81
Eosinophils, Within-Above [N=85;87;85;91]	2	1	3	3
Eosinophils, Above-Below [N=2;0;0;0]	0	0	0	0
Eosinophils, Above-Within [N=2;0;0;0]	0	0	0	0
Eosinophils, Above-Above [N=2;0;0;0]	2	0	0	0
Hemoglobin, Unknown-Below [N=1;0;0;1]	0	0	0	0
Hemoglobin, Unknown-Within [N=1;0;0;1]	1	0	0	1
Hemoglobin, Unknown-Above [N=1;0;0;1]	0	0	0	0
Hemoglobin, Below-Below [N=20;11;8;11]	13	6	5	8
Hemoglobin, Below-Within [N=20;11;8;11]	7	5	3	3
Hemoglobin, Below-Above [N=20;11;8;11]	0	0	0	0
Hemoglobin, Within-Below [N=79;82;90;89]	5	4	6	7
Hemoglobin, Within-Within [N=79;82;90;89]	74	78	84	81
Hemoglobin, Within-Above [N=79;82;90;89]	0	0	0	1
Hemoglobin, Above-Below [N=0;2;0;0]	0	0	0	0
Hemoglobin, Above-Within [N=0;2;0;0]	0	1	0	0
Hemoglobin, Above-Above [N=0;2;0;0]	0	1	0	0
Lymphocytes, Unknown-Below [N=1;0;1;1]	0	0	0	0
Lymphocytes, Unknown-Within [N=1;0;1;1]	1	0	1	1
Lymphocytes, Unknown-Above [N=1;0;1;1]	0	0	0	0
Lymphocytes, Below-Below [N=1;0;0;1]	0	0	0	0

Lymphocytes, Below-Within [N=1;0;0;1]	1	0	0	1
Lymphocytes, Below-Above [N=1;0;0;1]	0	0	0	0
Lymphocytes, Within-Below [N=97;94;95;99]	1	0	1	0
Lymphocytes, Within-Within [N=97;94;95;99]	96	94	93	96
Lymphocytes, Within-Above [N=97;94;95;99]	0	0	1	3
Lymphocytes, Above-Below [N=1;1;0;0]	0	0	0	0
Lymphocytes, Above-Within [N=1;1;0;0]	1	1	0	0
Lymphocytes, Above-Above [N=1;1;0;0]	0	0	0	0
Neutrophils, Unknown-Below [N=1;0;1;1]	0	0	0	0
Neutrophils, Unknown-Within [N=1;0;1;1]	1	0	1	1
Neutrophils, Unknown-Above [N=1;0;1;1]	0	0	0	0
Neutrophils, Below-Below [N=4;1;0;3]	0	0	0	1
Neutrophils, Below-Within [N=4;1;0;3]	4	1	0	2
Neutrophils, Below-Above [N=4;1;0;3]	0	0	0	0
Neutrophils, Within-Below [N=95;90;92;96]	4	4	4	4
Neutrophils, Within-Within [N=95;90;92;96]	89	84	88	89
Neutrophils, Within-Above [N=95;90;92;96]	2	2	0	3
Neutrophils, Above-Below [N=0;4;3;1]	0	0	0	0
Neutrophils, Above-Within [N=0;4;3;1]	0	4	3	1
Neutrophils, Above-Above [N=0;4;3;1]	0	0	0	0
Platelet count, Unknown-Below [N=2;2;0;1]	0	0	0	0
Platelet count, Unknown-Within [N=2;2;0;1]	2	2	0	1
Platelet count, Unknown-Above [N=2;2;0;1]	0	0	0	0
Platelet count, Below-Below [N=0;0;0;0]	0	0	0	0
Platelet count, Below-Within [N=0;0;0;0]	0	0	0	0
Platelet count, Below-Above [N=0;0;0;0]	0	0	0	0
Platelet count, Within-Below [N=94;93;98;99]	0	0	1	0
Platelet count, Within-Within [N=94;93;98;99]	93	92	97	98
Platelet count, Within-Above [N=94;93;98;99]	1	1	0	1
Platelet count, Above-Below [N=1;0;0;1]	0	0	0	0
Platelet count, Above-Within [N=1;0;0;1]	1	0	0	1
Platelet count, Above-Above [N=1;0;0;1]	0	0	0	0
WBC, Unknown-Below [N=1;0;0;1]	0	0	0	0
WBC, Unknown-Within [N=1;0;0;1]	1	0	0	1

WBC, Unknown-Above [N=1;0;0;1]	0	0	0	0
WBC, Below-Below [N=3;0;2;5]	1	0	2	3
WBC, Below-Within [N=3;0;2;5]	2	0	0	2
WBC, Below-Above [N=3;0;2;5]	0	0	0	0
WBC, Within-Below [N=96;91;93;94]	2	1	2	1
WBC, Within-Within [N=96;91;93;94]	92	86	90	87
WBC, Within-Above [N=96;91;93;94]	2	4	1	6
WBC, Above-Below [N=0;4;3;1]	0	0	0	0
WBC, Above-Within [N=0;4;3;1]	0	3	2	1
WBC, Above-Above [N=0;4;3;1]	0	1	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any biochemical and hematological laboratory abnormalities

End point title	Number of subjects with any biochemical and hematological laboratory abnormalities

End point description:

Biochemical parameters assessed included alanine aminotransferase [ALT], aspartate aminotransferase [AST] and creatinine. Hematological parameters assessed included eosinophils, hemoglobin level, lymphocytes, neutrophils, platelet count and White Blood Cells [WBC]. Abnormal laboratory values at Day 90 were Below, Within and Above normal ranges, as compared to the baseline status of the same parameter, at Day 0 (Unknown, Below, Within and Above normal ranges) [e.g. ALT Below - Within = ALT with below normal value at baseline and within normal values at Day 90].

End point type	Secondary

End point timeframe:

At Day 90

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	97	97	99
Units: Participants				
ALT, Below-Below [N=0;0;0;0]	0	0	0	0
ALT, Below-Within [N=0;0;0;0]	0	0	0	0
ALT, Below-Above [N=0;0;0;0]	0	0	0	0
ALT, Within-Below [N=99;95;97;99]	0	0	0	0
ALT, Within-Within [N=99;95;97;99]	98	95	97	99
ALT, Within-Above [N=99;95;97;99]	1	0	0	0
ALT, Above-Below [N=1;1;0;0]	0	0	0	0
ALT, Above-Within [N=1;1;0;0]	1	1	0	0
ALT, Above-Above [N=1;1;0;0]	0	0	0	0
AST, Below-Below [N=0;0;0;0]	0	0	0	0
AST, Below-Within [N=0;0;0;0]	0	0	0	0
AST, Below-Above [N=0;0;0;0]	0	0	0	0

AST, Within-Below [N=99;95;97;98]	0	0	0	0
AST, Within-Within [N=99;95;97;98]	99	95	97	98
AST, Within-Above [N=99;95;97;98]	0	0	0	0
AST, Above-Below [N=1;1;0;1]	0	0	0	0
AST, Above-Within [N=1;1;0;1]	1	1	0	1
AST, Above-Above [N=1;1;0;1]	0	0	0	0
Creatinine, Below-Below [N=6;5;2;2]	1	2	2	2
Creatinine, Below-Within [N=6;5;2;2]	5	3	0	0
Creatinine, Below-Above [N=6;5;2;2]	0	0	0	0
Creatinine, Within-Below [N=93;90;95;96]	3	2	4	3
Creatinine, Within-Within [N=93;90;95;96]	90	88	91	92
Creatinine, Within-Above [N=93;90;95;96]	0	0	0	1
Creatinine, Above-Below [N=1;1;0;1]	0	0	0	0
Creatinine, Above-Within [N=1;1;0;1]	1	0	0	1
Creatinine, Above-Above [N=1;1;0;1]	0	1	0	0
Eosinophils, Unknown-Below [N=1;1;1;1]	0	0	0	0
Eosinophils, Unknown-Within [N=1;1;1;1]	1	1	1	1
Eosinophils, Unknown-Above [N=1;1;1;1]	0	0	0	0
Eosinophils, Below-Below [N=12;8;11;9]	6	2	4	4
Eosinophils, Below-Within [N=12;8;11;9]	6	6	7	5
Eosinophils, Below-Above [N=12;8;11;9]	0	0	0	0
Eosinophils, Within-Below [N=84;87;80;89]	6	5	8	9
Eosinophils, Within-Within [N=84;87;80;89]	76	81	70	80
Eosinophils, Within-Above [N=84;87;80;89]	2	1	2	0
Eosinophils, Above-Below [N=2;0;0;0]	0	0	0	0
Eosinophils, Above-Within [N=2;0;0;0]	2	0	0	0
Eosinophils, Above-Above [N=2;0;0;0]	0	0	0	0
Hemoglobin, Unknown-Below [N=1;0;0;1]	0	0	0	0
Hemoglobin, Unknown-Within [N=1;0;0;1]	1	0	0	1
Hemoglobin, Unknown-Above [N=1;0;0;1]	0	0	0	0
Hemoglobin, Below-Below [N=20;11;7;11]	11	5	6	7
Hemoglobin, Below-Within [N=20;11;7;11]	9	6	1	4
Hemoglobin, Below-Above [N=20;11;7;11]	0	0	0	0
Hemoglobin, Within-Below [N=79;84;89;87]	4	3	4	5
Hemoglobin, Within-Within [N=79;84;89;87]	75	81	84	82
Hemoglobin, Within-Above [N=79;84;89;87]	0	0	1	0
Hemoglobin, Above-Below [N=0;2;0;0]	0	0	0	0
Hemoglobin, Above-Within [N=0;2;0;0]	0	1	0	0

Hemoglobin, Above-Above [N=0;2;0;0]	0	1	0	0
Lymphocytes, Unknown-Below [N=1;1;1;1]	0	0	0	0
Lymphocytes, Unknown-Within [N=1;1;1;1]	1	1	1	1
Lymphocytes, Unknown-Above [N=1;1;1;1]	0	0	0	0
Lymphocytes, Below-Below [N=1;0;0;1]	0	0	0	1
Lymphocytes, Below-Within [N=1;0;0;1]	1	0	0	0
Lymphocytes, Below-Above [N=1;0;0;1]	0	0	0	0
Lymphocytes, Within-Below [N=96;94;91;97]	1	0	1	1
Lymphocytes, Within-Within [N=96;94;91;97]	95	93	90	95
Lymphocytes, Within-Above [N=96;94;91;97]	0	1	0	1
Lymphocytes, Above-Below [N=1;1;0;0]	0	0	0	0
Lymphocytes, Above-Within [N=1;1;0;0]	1	0	0	0
Lymphocytes, Above-Above [N=1;1;0;0]	0	1	0	0
Neutrophils, Unknown-Below [N=1;1;1;1]	0	0	0	0
Neutrophils, Unknown-Within [N=1;1;1;1]	1	1	1	1
Neutrophils, Unknown-Above [N=1;1;1;1]	0	0	0	0
Neutrophils, Below-Below [N=4;1;0;3]	2	0	0	1
Neutrophils, Below-Within [N=4;1;0;3]	2	1	0	2
Neutrophils, Below-Above [N=4;1;0;3]	0	0	0	0
Neutrophils, Within-Below [N=94;90;88;94]	3	5	2	1
Neutrophils, Within-Within [N=94;90;88;94]	89	83	86	91
Neutrophils, Within-Above [N=94;90;88;94]	2	2	0	2
Neutrophils, Above-Below [N=0;4;3;1]	0	0	0	0
Neutrophils, Above-Within [N=0;4;3;1]	0	4	3	0
Neutrophils, Above-Above [N=0;4;3;1]	0	0	0	1
Platelet count, Unknown-Below [N=3;2;0;1]	1	0	0	0
Platelet count, Unknown-Within [N=3;2;0;1]	2	2	0	1
Platelet count, Unknown-Above [N=3;2;0;1]	0	0	0	0
Platelet count, Below-Below [N=0;0;0;0]	0	0	0	0
Platelet count, Below-Within [N=0;0;0;0]	0	0	0	0
Platelet count, Below-Above [N=0;0;0;0]	0	0	0	0
Platelet count, Within-Below [N=94;94;96;95]	0	1	0	0
Platelet count, Within-Within [N=94;94;96;95]	91	91	95	95
Platelet count, Within-Above [N=94;94;96;95]	3	2	1	0

Platelet count, Above-Below [N=1;0;0;1]	0	0	0	0
Platelet count, Above-Within [N=1;0;0;1]	1	0	0	1
Platelet count, Above-Above [N=1;0;0;1]	0	0	0	0
WBC, Unknown-Below [N=1;0;0;1]	0	0	0	0
WBC, Unknown-Within [N=1;0;0;1]	1	0	0	1
WBC, Unknown-Above [N=1;0;0;1]	0	0	0	0
WBC, Below-Below [N=3;0;2;5]	1	0	1	1
WBC, Below-Within [N=3;0;2;5]	2	0	1	4
WBC, Below-Above [N=3;0;2;5]	0	0	0	0
WBC, Within-Below [N=96;93;91;92]	2	1	1	0
WBC, Within-Within [N=96;93;91;92]	91	89	89	89
WBC, Within-Above [N=96;93;91;92]	3	3	1	3
WBC, Above-Below [N=0;4;3;1]	0	0	0	0
WBC, Above-Within [N=0;4;3;1]	0	3	3	0
WBC, Above-Above [N=0;4;3;1]	0	1	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any biochemical and hematological laboratory abnormalities, by maximum grading

End point title	Number of subjects with any biochemical and hematological laboratory abnormalities, by maximum grading

End point description:

The biochemical and hematological parameters analyzed were ALT, AST, creatinine, eosinophils increase, hemoglobin decrease, lymphocytes decrease, neutrophils decrease, platelet count decrease, WBC decrease and WBC increase, which were graded by FDA Toxicity Grading Scale. Assessed grades over the Day 7- Day 90 period were Unknown (U), Grade 0 (G0=no grade), Grade 1 (G1=mild), Grade 2 (G2=moderate), Grade 3 (G3=severe) and Grade 4 (G4=potentially life-threatening), as compared to the baseline status of the same parameters, at Day 0 (Unknown, Grade 1, Grade 2, Grade 3) [e.g. ALT Grade 0 - Unknown = ALT Grade 0 at baseline versus Unknown grade from Day 7 up to Day 90].

End point type	Secondary

End point timeframe:

From Day 7 up to Day 90

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	98	99	102
Units: Participants				
ALT, G0-U [N=99;97;99;102]	0	0	0	0
ALT, G0-G0 [N=99;97;99;102]	96	97	96	101
ALT, G0-G1 [N=99;97;99;102]	2	0	3	1
ALT, G0-G2 [N=99;97;99;102]	0	0	0	0

ALT, G0-G3 [N=99;97;99;102]	1	0	0	0
ALT, G0-G4 [N=99;97;99;102]	0	0	0	0
ALT, G1-U [N=1;0;0;0]	0	0	0	0
ALT, G1-G0 [N=1;0;0;0]	1	0	0	0
ALT, G1-G1 [N=1;0;0;0]	0	0	0	0
ALT, G1-G2 [N=1;0;0;0]	0	0	0	0
ALT, G1-G3 [N=1;0;0;0]	0	0	0	0
ALT, G1-G4 [N=1;0;0;0]	0	0	0	0
ALT, G2-U [N=0;1;0;0]	0	0	0	0
ALT, G2-G0 [N=0;1;0;0]	0	0	0	0
ALT, G2-G1 [N=0;1;0;0]	0	0	0	0
ALT, G2-G2 [N=0;1;0;0]	0	1	0	0
ALT, G2-G3 [N=0;1;0;0]	0	0	0	0
ALT, G2-G4 [N=0;1;0;0]	0	0	0	0
AST, G0-U [N=100;97;99;101]	0	0	0	0
AST, G0-G0 [N=100;97;99;101]	98	97	97	101
AST, G0-G1 [N=100;97;99;101]	0	0	2	0
AST, G0-G2 [N=100;97;99;101]	1	0	0	0
AST, G0-G3 [N=100;97;99;101]	0	0	0	0
AST, G0-G4 [N=100;97;99;101]	1	0	0	0
AST, G1-U [N=0;1;0;1]	0	0	0	0
AST, G1-G0 [N=0;1;0;1]	0	0	0	1
AST, G1-G1 [N=0;1;0;1]	0	0	0	0
AST, G1-G2 [N=0;1;0;1]	0	1	0	0
AST, G1-G3 [N=0;1;0;1]	0	0	0	0
AST, G1-G4 [N=0;1;0;1]	0	0	0	0
Creatinine, G0-U [N=100;98;99;102]	0	0	0	0
Creatinine, G0-G0 [N=100;98;99;102]	100	98	99	102
Creatinine, G0-G1 [N=100;98;99;102]	0	0	0	0
Creatinine, G0-G2 [N=100;98;99;102]	0	0	0	0
Creatinine, G0-G3 [N=100;98;99;102]	0	0	0	0
Creatinine, G0-G4 [N=100;98;99;102]	0	0	0	0
Eosinophils increase, U-U [N=1;1;1;1]	0	0	0	0
Eosinophils increase, U-G0 [N=1;1;1;1]	1	1	1	1
Eosinophils increase, U-G1 [N=1;1;1;1]	0	0	0	0
Eosinophils increase, U-G2 [N=1;1;1;1]	0	0	0	0
Eosinophils increase, U-G3 [N=1;1;1;1]	0	0	0	0
Eosinophils increase, U-G4 [N=1;1;1;1]	0	0	0	0
Eosinophils increase, G0-U [N=97;97;98;101]	0	0	0	0
Eosinophils increase, G0-G0 [N=97;97;98;101]	94	96	95	99
Eosinophils increase, G0-G1 [N=97;97;98;101]	3	1	3	2
Eosinophils increase, G0-G2 [N=97;97;98;101]	0	0	0	0
Eosinophils increase, G0-G3 [N=97;97;98;101]	0	0	0	0
Eosinophils increase, G0-G4 [N=97;97;98;101]	0	0	0	0
Eosinophils increase, G1-U [N=1;0;0;0]	0	0	0	0
Eosinophils increase, G1-G0 [N=1;0;0;0]	0	0	0	0

Eosinophils increase, G1-G1 [N=1;0;0;0]	1	0	0	0
Eosinophils increase, G1-G2 [N=1;0;0;0]	0	0	0	0
Eosinophils increase, G1-G3 [N=1;0;0;0]	0	0	0	0
Eosinophils increase, G1-G4 [N=1;0;0;0]	0	0	0	0
Eosinophils increase, G2-U [N=1;0;0;0]	0	0	0	0
Eosinophils increase, G2-G0 [N=1;0;0;0]	0	0	0	0
Eosinophils increase, G2-G1 [N=1;0;0;0]	0	0	0	0
Eosinophils increase, G2-G2 [N=1;0;0;0]	1	0	0	0
Eosinophils increase, G2-G3 [N=1;0;0;0]	0	0	0	0
Eosinophils increase, G2-G4 [N=1;0;0;0]	0	0	0	0
Hemoglobin decrease, U-U [N=1;0;0;1]	0	0	0	0
Hemoglobin decrease, U-G0 [N=1;0;0;1]	1	0	0	1
Hemoglobin decrease, U-G1 [N=1;0;0;1]	0	0	0	0
Hemoglobin decrease, U-G2 [N=1;0;0;1]	0	0	0	0
Hemoglobin decrease, U-G3 [N=1;0;0;1]	0	0	0	0
Hemoglobin decrease, U-G4 [N=1;0;0;1]	0	0	0	0
Hemoglobin decrease, G0-U [N=78;86;88;88]	0	0	0	0
Hemoglobin decrease, G0-G0 [N=78;86;88;88]	61	74	73	74
Hemoglobin decrease, G0-G1 [N=78;86;88;88]	14	12	15	13
Hemoglobin decrease, G0-G2 [N=78;86;88;88]	2	0	0	1
Hemoglobin decrease, G0-G3 [N=78;86;88;88]	1	0	0	0
Hemoglobin decrease, G0-G4 [N=78;86;88;88]	0	0	0	0
Hemoglobin decrease, G1-U [N=19;12;9;12]	0	0	0	0
Hemoglobin decrease, G1-G0 [N=19;12;9;12]	3	2	2	0
Hemoglobin decrease, G1-G1 [N=19;12;9;12]	11	9	5	10
Hemoglobin decrease, G1-G2 [N=19;12;9;12]	5	1	2	2
Hemoglobin decrease, G1-G3 [N=19;12;9;12]	0	0	0	0
Hemoglobin decrease, G1-G4 [N=19;12;9;12]	0	0	0	0
Hemoglobin decrease, G2-U [N=1;0;2;1]	0	0	0	0
Hemoglobin decrease, G2-G0 [N=1;0;2;1]	0	0	0	0
Hemoglobin decrease, G2-G1 [N=1;0;2;1]	0	0	1	0
Hemoglobin decrease, G2-G2 [N=1;0;2;1]	1	0	1	1

Hemoglobin decrease, G2-G3 [N=1;0;2;1]	0	0	0	0
Hemoglobin decrease, G2-G4 [N=1;0;2;1]	0	0	0	0
Hemoglobin decrease, G3-U [N=1;0;0;0]	0	0	0	0
Hemoglobin decrease, G3-G0 [N=1;0;0;0]	0	0	0	0
Hemoglobin decrease, G3-G1 [N=1;0;0;0]	0	0	0	0
Hemoglobin decrease, G3-G2 [N=1;0;0;0]	1	0	0	0
Hemoglobin decrease, G3-G3 [N=1;0;0;0]	0	0	0	0
Hemoglobin decrease, G3-G4 [N=1;0;0;0]	0	0	0	0
Lymphocytes decrease, U-U [N=1;1;1;1]	0	0	0	0
Lymphocytes decrease, U-G0 [N=1;1;1;1]	1	1	1	1
Lymphocytes decrease, U-G1 [N=1;1;1;1]	0	0	0	0
Lymphocytes decrease, U-G2 [N=1;1;1;1]	0	0	0	0
Lymphocytes decrease, U-G3 [N=1;1;1;1]	0	0	0	0
Lymphocytes decrease, U-G4 [N=1;1;1;1]	0	0	0	0
Lymphocytes decrease, G0-U [N=96;97;97;100]	0	0	0	0
Lymphocytes decrease, G0-G0 [N=96;97;97;100]	90	97	93	99
Lymphocytes decrease, G0-G1 [N=96;97;97;100]	5	0	4	1
Lymphocytes decrease, G0-G2 [N=96;97;97;100]	1	0	0	0
Lymphocytes decrease, G0-G3 [N=96;97;97;100]	0	0	0	0
Lymphocytes decrease, G0-G4 [N=96;97;97;100]	0	0	0	0
Lymphocytes decrease, G1-U [N=2;0;1;0]	0	0	0	0
Lymphocytes decrease, G1-G0 [N=2;0;1;0]	1	0	1	0
Lymphocytes decrease, G1-G1 [N=2;0;1;0]	1	0	0	0
Lymphocytes decrease, G1-G2 [N=2;0;1;0]	0	0	0	0
Lymphocytes decrease, G1-G3 [N=2;0;1;0]	0	0	0	0
Lymphocytes decrease, G1-G4 [N=2;0;1;0]	0	0	0	0
Lymphocytes decrease, G2-U [N=1;0;0;1]	0	0	0	0
Lymphocytes decrease, G2-G0 [N=1;0;0;1]	0	0	0	0
Lymphocytes decrease, G2-G1 [N=1;0;0;1]	1	0	0	1
Lymphocytes decrease, G2-G2 [N=1;0;0;1]	0	0	0	0
Lymphocytes decrease, G2-G3 [N=1;0;0;1]	0	0	0	0

Lymphocytes decrease, G2-G4 [N=1;0;0;1]	0	0	0	0
Neutrophils decrease, U-U [N=1;1;1;1]	0	0	0	0
Neutrophils decrease, U-G0 [N=1;1;1;1]	1	1	0	1
Neutrophils decrease, U-G1 [N=1;1;1;1]	0	0	1	0
Neutrophils decrease, U-G2 [N=1;1;1;1]	0	0	0	0
Neutrophils decrease, U-G3 [N=1;1;1;1]	0	0	0	0
Neutrophils decrease, U-G4 [N=1;1;1;1]	0	0	0	0
Neutrophils decrease, G0-U [N=94;95;95;95]	0	0	0	0
Neutrophils decrease, G0-G0 [N=94;95;95;95]	80	70	82	82
Neutrophils decrease, G0-G1 [N=94;95;95;95]	10	20	11	8
Neutrophils decrease, G0-G2 [N=94;95;95;95]	3	5	2	5
Neutrophils decrease, G0-G3 [N=94;95;95;95]	1	0	0	0
Neutrophils decrease, G0-G4 [N=94;95;95;95]	0	0	0	0
Neutrophils decrease, G1-U [N=2;1;3;4]	0	0	0	0
Neutrophils decrease, G1-G0 [N=2;1;3;4]	0	1	3	2
Neutrophils decrease, G1-G1 [N=2;1;3;4]	1	0	0	1
Neutrophils decrease, G1-G2 [N=2;1;3;4]	1	0	0	1
Neutrophils decrease, G1-G3 [N=2;1;3;4]	0	0	0	0
Neutrophils decrease, G1-G4 [N=2;1;3;4]	0	0	0	0
Neutrophils decrease, G2-U [N=3;1;0;2]	0	0	0	0
Neutrophils decrease, G2-G0 [N=3;1;0;2]	0	0	0	0
Neutrophils decrease, G2-G1 [N=3;1;0;2]	1	1	0	1
Neutrophils decrease, G2-G2 [N=3;1;0;2]	2	0	0	1
Neutrophils decrease, G2-G3 [N=3;1;0;2]	0	0	0	0
Neutrophils decrease, G2-G4 [N=3;1;0;2]	0	0	0	0
Platelet count decrease, U-U [N=4;2;0;1]	1	0	0	0
Platelet count decrease, U-G0 [N=4;2;0;1]	2	2	0	1
Platelet count decrease, U-G1 [N=4;2;0;1]	0	0	0	0
Platelet count decrease, U-G2 [N=4;2;0;1]	0	0	0	0
Platelet count decrease, U-G3 [N=4;2;0;1]	1	0	0	0
Platelet count decrease, U-G4 [N=4;2;0;1]	0	0	0	0

Platelet count decrease, G0-U [N=96;95;99;101]	0	0	0	0
Platelet count decrease, G0-G0 [N=96;95;99;101]	94	94	97	100
Platelet count decrease, G0-G1 [N=96;95;99;101]	1	1	1	1
Platelet count decrease, G0-G2 [N=96;95;99;101]	1	0	1	0
Platelet count decrease, G0-G3 [N=96;95;99;101]	0	0	0	0
Platelet count decrease, G0-G4 [N=96;95;99;101]	0	0	0	0
Platelet count decrease, G1-U [N=0;1;0;0]	0	0	0	0
Platelet count decrease, G1-G0 [N=0;1;0;0]	0	0	0	0
Platelet count decrease, G1-G1 [N=0;1;0;0]	0	1	0	0
Platelet count decrease, G1-G2 [N=0;1;0;0]	0	0	0	0
Platelet count decrease, G1-G3 [N=0;1;0;0]	0	0	0	0
Platelet count decrease, G1-G4 [N=0;1;0;0]	0	0	0	0
WBC decrease, U-U [N=1;0;0;1]	0	0	0	0
WBC decrease, U-G0 [N=1;0;0;1]	1	0	0	1
WBC decrease, U-G1 [N=1;0;0;1]	0	0	0	0
WBC decrease, U-G2 [N=1;0;0;1]	0	0	0	0
WBC decrease, U-G3 [N=1;0;0;1]	0	0	0	0
WBC decrease, U-G4 [N=1;0;0;1]	0	0	0	0
WBC decrease, G0-U [N=98;98;98;98]	0	0	0	0
WBC decrease, G0-G0 [N=98;98;98;98]	92	95	94	94
WBC decrease, G0-G1 [N=98;98;98;98]	6	3	4	4
WBC decrease, G0-G2 [N=98;98;98;98]	0	0	0	0
WBC decrease, G0-G3 [N=98;98;98;98]	0	0	0	0
WBC decrease, G0-G4 [N=98;98;98;98]	0	0	0	0
WBC decrease, G1-U [N=1;0;1;3]	0	0	0	0
WBC decrease, G1-G0 [N=1;0;1;3]	0	0	0	0
WBC decrease, G1-G1 [N=1;0;1;3]	1	0	0	3
WBC decrease, G1-G2 [N=1;0;1;3]	0	0	1	0
WBC decrease, G1-G3 [N=1;0;1;3]	0	0	0	0
WBC decrease, G1-G4 [N=1;0;1;3]	0	0	0	0
WBC increase, U-U [N=1;0;0;1]	0	0	0	0
WBC increase, U-G0 [N=1;0;0;1]	1	0	0	1
WBC increase, U-G1 [N=1;0;0;1]	0	0	0	0
WBC increase, U-G2 [N=1;0;0;1]	0	0	0	0
WBC increase, U-G3 [N=1;0;0;1]	0	0	0	0
WBC increase, U-G4 [N=1;0;0;1]	0	0	0	0
WBC increase, G0-U [N=99;94;96;99]	0	0	0	0
WBC increase, G0-G0 [N=99;94;96;99]	95	85	91	88
WBC increase, G0-G1 [N=99;94;96;99]	3	9	5	11
WBC increase, G0-G2 [N=99;94;96;99]	1	0	0	0
WBC increase, G0-G3 [N=99;94;96;99]	0	0	0	0
WBC increase, G0-G4 [N=99;94;96;99]	0	0	0	0
WBC increase, G1-U [N=0;4;2;2]	0	0	0	0
WBC increase, G1-G0 [N=0;4;2;2]	0	1	1	1

WBC increase, G1-G1 [N=0;4;2;2]	0	3	1	0
WBC increase, G1-G2 [N=0;4;2;2]	0	0	0	1
WBC increase, G1-G3 [N=0;4;2;2]	0	0	0	0
WBC increase, G1-G4 [N=0;4;2;2]	0	0	0	0
WBC increase, G2-U [N=0;0;1;0]	0	0	0	0
WBC increase, G2-G0 [N=0;0;1;0]	0	0	0	0
WBC increase, G2-G1 [N=0;0;1;0]	0	0	1	0
WBC increase, G2-G2 [N=0;0;1;0]	0	0	0	0
WBC increase, G2-G3 [N=0;0;1;0]	0	0	0	0
WBC increase, G2-G4 [N=0;0;1;0]	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Neutralizing antibody titers against RSV-A subtype

End point title	Neutralizing antibody titers against RSV-A subtype

End point description:

RSV-A is one of the two antigenically distinct subgroups of the Respiratory Synctial Virus (RSV). Antibody titers were determined by neutralization assay and presented as geometric mean titers (GMTs), for a seropositivity cut-off value ≥ 8 ED60.

End point type	Secondary

End point timeframe:

At Day 60 and Day 90

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	92	96	96
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-RSV.A, Day 30 [N=98;92;96;96]	715.4 (615.8 to 831.1)	831.9 (733.0 to 944.1)	965.1 (827.7 to 1125.4)	311.6 (269.0 to 360.8)
Anti-RSV.A, Day 90 [N=98;92;95;95]	566.5 (494.9 to 648.4)	732.1 (640.2 to 837.2)	902.8 (776.4 to 1049.9)	319.6 (274.2 to 372.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Neutralizing antibody titers against RSV-B subtype

End point title	Neutralizing antibody titers against RSV-B subtype

End point description:

RSV-B is one of the two antigenically distinct subgroups of the Respiratory Synctial Virus (RSV). Antibody titers were determined by neutralization assay and presented as geometric mean titers (GMTs), for a seropositivity cut-off value ≥ 6 ED60.

End point type	Secondary

End point timeframe:

At Day 0, Day 30, Day 60 and Day 90

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	95	98	100
Units: Titers				
geometric mean (confidence interval 95%)				
Anti-RSV.B, Day 0 [N=98;95;98;100]	385.6 (318.4 to 466.9)	392.1 (334.3 to 460.0)	410.6 (346.5 to 486.5)	340.2 (289.0 to 400.4)
Anti-RSV.B, Day 30 [N=98;94;98;100]	909.1 (778.5 to 1061.6)	1004.1 (886.5 to 1137.4)	1131.7 (987.3 to 1297.2)	357.7 (309.0 to 414.0)
Anti-RSV.B, Day 60 [N=98;92;96;96]	752.1 (646.7 to 874.6)	847.1 (746.8 to 960.9)	923.6 (813.2 to 1048.8)	409.6 (359.2 to 467.1)
Anti-RSV.B, Day 90 [N=98;92;95;95]	667.8 (572.8 to 778.7)	804.9 (699.4 to 926.3)	848.6 (731.4 to 984.7)	423.2 (359.2 to 498.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Palivizumab competing antibody (PCA) concentrations

End point title	Palivizumab competing antibody (PCA) concentrations

End point description:

PCA concentrations were determined by Enzyme-Linked Immunosorbent Assay (ELISA), presented as geometric mean concentrations (GMCs) and expressed in micrograms per milliliter (µg/mL), for a seropositivity cut-off value ≥ 9.6 µg/mL.

End point type	Secondary

End point timeframe:

At Day 60 and Day 90

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	98	92	96	96
Units: µg/mL				
geometric mean (confidence interval				

95%)				
PCA, Day 60 [N=98;92;96;96]	55.2 (48.8 to 62.5)	69.0 (62.4 to 76.4)	66.7 (58.7 to 75.8)	6.4 (5.8 to 7.1)
PCA, Day 90 [N=98;92;94;95]	47.6 (42.3 to 53.5)	57.9 (51.4 to 65.1)	57.0 (50.0 to 64.9)	7.4 (6.5 to 8.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Antibody concentrations against neogenin (NEO) residual host cell protein

End point title	Antibody concentrations against neogenin (NEO) residual host cell protein

End point description:

Anti-neogenin (anti-NEO) antibody concentrations were determined by ELISA, presented as geometric mean concentrations (GMCs) and expressed in nanograms per milliliter (ng/mL), for a seropositivity cut-off value ≥ 55 ng/mL.

End point type	Secondary

End point timeframe:

At Day 0 and Day 30

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	99	99	102
Units: ng/mL				
geometric mean (confidence interval 95%)				
Anti-NEO, Day 0 [N=100;99;97;102]	32.9 (29.2 to 37.1)	32.0 (28.7 to 35.7)	33.5 (29.3 to 38.3)	34.5 (30.0 to 39.5)
Anti-NEO, Day 30 [N=100;98;99;102]	32.9 (29.5 to 36.7)	31.5 (28.4 to 34.9)	33.1 (29.3 to 37.4)	34.7 (30.2 to 39.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any medically attended (MA) respiratory tract infections (RTIs) associated with RSV

End point title	Number of subjects with any medically attended (MA) respiratory tract infections (RTIs) associated with RSV

End point description:

MA-RSV-RTIs were defined as a visit to a health care provider for respiratory symptoms including but not limited to cough, sputum production, difficulty breathing.

End point type	Secondary

End point timeframe:

From Day 0 up to study end, at Day 360

End point values	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	100	99	99	102
Units: Participants				
Participants	21	11	10	9

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Solicited and unsolicited symptoms: during the 30-day (Days 0-29) post-vaccination period; SAEs: during the entire study period (Day 0-Day 360).	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups	
Reporting group title	GSK3003891A vaccine formulation 1 Group
Reporting group description:	
Subjects in this group received a single 30µg dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	GSK3003891A vaccine formulation 2 Group
Reporting group description:	
Subjects in this group received a single 60µg dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	GSK3003891A vaccine formulation 3 Group
Reporting group description:	
Subjects in this group received a single 120µg dose injection of the investigational GSK3003891A vaccine at Day 0.	
Reporting group title	Control Group
Reporting group description:	
Subjects in this group received a single placebo injection at Day 0.	

Serious adverse events	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 100 (1.00%)	3 / 99 (3.03%)	2 / 99 (2.02%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung adenocarcinoma			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (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
Pancreatic carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Hemiparesis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (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
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (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, thoracic and mediastinal disorders			
Pneumothorax			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (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 and connective tissue disorders			
Rheumatoid arthritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonsillar abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (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

Soft tissue infection			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (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

Serious adverse events	Control Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 102 (1.96%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lung adenocarcinoma			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatic carcinoma			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Hemiparesis			
subjects affected / exposed	0 / 102 (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 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary colic			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			

Pneumothorax			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Rheumatoid arthritis			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Campylobacter gastroenteritis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peritonsillar abscess			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Soft tissue infection			
subjects affected / exposed	0 / 102 (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: 0 %

Non-serious adverse events	GSK3003891A vaccine formulation 1 Group	GSK3003891A vaccine formulation 2 Group	GSK3003891A vaccine formulation 3 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	88 / 100 (88.00%)	86 / 99 (86.87%)	83 / 99 (83.84%)
Pregnancy, puerperium and perinatal conditions			
Retained placenta or membranes			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	2 / 100 (2.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	2	2	0
Axillary pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	3 / 99 (3.03%)
occurrences (all)	0	0	3
Chills			
subjects affected / exposed	1 / 100 (1.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	47 / 100 (47.00%)	43 / 99 (43.43%)	45 / 99 (45.45%)
occurrences (all)	48	43	46
Feeling cold			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	1 / 100 (1.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	1	1	0
Injection site haematoma			
subjects affected / exposed	0 / 100 (0.00%)	2 / 99 (2.02%)	0 / 99 (0.00%)
occurrences (all)	0	2	0
Injection site haemorrhage			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	3 / 99 (3.03%)
occurrences (all)	1	0	3
Injection site pruritus			
subjects affected / exposed	2 / 100 (2.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	2	1	0
Malaise			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	52 / 100 (52.00%)	52 / 99 (52.53%)	51 / 99 (51.52%)
occurrences (all)	53	52	51

Pyrexia			
subjects affected / exposed	8 / 100 (8.00%)	8 / 99 (8.08%)	6 / 99 (6.06%)
occurrences (all)	8	8	6
Swelling			
subjects affected / exposed	4 / 100 (4.00%)	6 / 99 (6.06%)	7 / 99 (7.07%)
occurrences (all)	4	6	7
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	2 / 100 (2.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	2	1	0
Menstrual disorder			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Ovarian cyst			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Polymenorrhoea			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Premenstrual pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 100 (5.00%)	2 / 99 (2.02%)	5 / 99 (5.05%)
occurrences (all)	5	2	5
Epistaxis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	2	0
Nasal congestion			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal pain			
subjects affected / exposed	9 / 100 (9.00%)	4 / 99 (4.04%)	4 / 99 (4.04%)
occurrences (all)	13	4	4
Pneumothorax			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Pulmonary mass			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Respiratory disorder			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Rhinitis allergic			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Sleep disorder			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Hepatic enzyme increased			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			

subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Contusion			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Ligament sprain			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Meniscus injury			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Muscle strain			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Post procedural inflammation			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Tooth fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Vaccination complication			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Cervicobrachial syndrome			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	1	0	1
Dizziness			

subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Facial neuralgia			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	54 / 100 (54.00%)	47 / 99 (47.47%)	47 / 99 (47.47%)
occurrences (all)	61	56	55
Hypoaesthesia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Intercostal neuralgia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Migraine			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	1 / 99 (1.01%)
occurrences (all)	0	1	2
Syncope			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 100 (0.00%)	2 / 99 (2.02%)	1 / 99 (1.01%)
occurrences (all)	0	2	1
Neutropenia			
subjects affected / exposed	1 / 100 (1.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	1	1	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Vertigo			

subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	3 / 99 (3.03%)
occurrences (all)	0	0	4
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	1	0	1
Abdominal pain upper			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Gastric disorder			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorder			
subjects affected / exposed	22 / 100 (22.00%)	24 / 99 (24.24%)	14 / 99 (14.14%)
occurrences (all)	22	24	14
Nausea			
subjects affected / exposed	2 / 100 (2.00%)	0 / 99 (0.00%)	2 / 99 (2.02%)
occurrences (all)	2	0	3
Toothache			

subjects affected / exposed	0 / 100 (0.00%)	2 / 99 (2.02%)	0 / 99 (0.00%)
occurrences (all)	0	2	0
Vomiting			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	6 / 100 (6.00%)	10 / 99 (10.10%)	8 / 99 (8.08%)
occurrences (all)	6	10	8
Pruritus			
subjects affected / exposed	2 / 100 (2.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	2	0	1
Rash			
subjects affected / exposed	2 / 100 (2.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	2	0	1
Rash vesicular			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	4 / 100 (4.00%)	2 / 99 (2.02%)	1 / 99 (1.01%)
occurrences (all)	4	3	1
Bone pain			

subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 100 (1.00%)	1 / 99 (1.01%)	2 / 99 (2.02%)
occurrences (all)	1	1	2
Neck pain			
subjects affected / exposed	1 / 100 (1.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	1	2	0
Pain in extremity			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Tendonitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	1 / 100 (1.00%)	3 / 99 (3.03%)	1 / 99 (1.01%)
occurrences (all)	1	4	1
Gastroenteritis			
subjects affected / exposed	3 / 100 (3.00%)	1 / 99 (1.01%)	1 / 99 (1.01%)
occurrences (all)	3	1	1
Gastroenteritis viral			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Genital herpes			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0

Herpes simplex			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	0	0	1
Infection			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Infective keratitis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	1 / 100 (1.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	1	1	0
Nasopharyngitis			
subjects affected / exposed	6 / 100 (6.00%)	3 / 99 (3.03%)	4 / 99 (4.04%)
occurrences (all)	7	3	4
Oral herpes			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	1 / 99 (1.01%)
occurrences (all)	2	0	1
Pharyngitis			
subjects affected / exposed	1 / 100 (1.00%)	1 / 99 (1.01%)	1 / 99 (1.01%)
occurrences (all)	1	1	1
Pulpitis dental			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	13 / 100 (13.00%)	3 / 99 (3.03%)	7 / 99 (7.07%)
occurrences (all)	14	4	7
Salpingo-oophoritis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Skin bacterial infection			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0

Tonsillitis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 99 (1.01%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 100 (3.00%)	9 / 99 (9.09%)	8 / 99 (8.08%)
occurrences (all)	3	10	8
Urinary tract infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal candidiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 99 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Control Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	76 / 102 (74.51%)		
Pregnancy, puerperium and perinatal conditions			
Retained placenta or membranes			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Axillary pain			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	42 / 102 (41.18%)		
occurrences (all)	42		
Feeling cold			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		

Gait disturbance subjects affected / exposed occurrences (all)	0 / 102 (0.00%) 0		
Influenza like illness subjects affected / exposed occurrences (all)	1 / 102 (0.98%) 1		
Injection site haematoma subjects affected / exposed occurrences (all)	0 / 102 (0.00%) 0		
Injection site haemorrhage subjects affected / exposed occurrences (all)	0 / 102 (0.00%) 0		
Injection site pruritus subjects affected / exposed occurrences (all)	1 / 102 (0.98%) 1		
Malaise subjects affected / exposed occurrences (all)	0 / 102 (0.00%) 0		
Pain subjects affected / exposed occurrences (all)	11 / 102 (10.78%) 12		
Pyrexia subjects affected / exposed occurrences (all)	4 / 102 (3.92%) 4		
Swelling subjects affected / exposed occurrences (all)	0 / 102 (0.00%) 0		
Reproductive system and breast disorders			
Dysmenorrhoea subjects affected / exposed occurrences (all)	1 / 102 (0.98%) 1		
Menstrual disorder subjects affected / exposed occurrences (all)	0 / 102 (0.00%) 0		
Ovarian cyst			

subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Polymenorrhoea			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Premenstrual pain			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	5 / 102 (4.90%)		
occurrences (all)	5		
Epistaxis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			
subjects affected / exposed	5 / 102 (4.90%)		
occurrences (all)	5		
Pneumothorax			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Pulmonary mass			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Respiratory disorder			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Rhinitis allergic			

subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Sleep disorder			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Investigations			
Haemoglobin decreased			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Hepatic enzyme increased			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Bone contusion			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Ligament sprain			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Meniscus injury			

subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Muscle strain			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Post procedural inflammation			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Tooth fracture			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Vaccination complication			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Cervicobrachial syndrome			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Facial neuralgia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	47 / 102 (46.08%)		
occurrences (all)	53		
Hypoaesthesia			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Intercostal neuralgia			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		

Migraine			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Syncope			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Lymphadenopathy			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	2 / 102 (1.96%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharospasm			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		

Constipation			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	2 / 102 (1.96%)		
occurrences (all)	2		
Dyspepsia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Gastric disorder			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorder			
subjects affected / exposed	11 / 102 (10.78%)		
occurrences (all)	11		
Nausea			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	2 / 102 (1.96%)		
occurrences (all)	2		
Vomiting			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Dermatitis			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Erythema			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Pruritus			

subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Rash vesicular			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Back pain			
subjects affected / exposed	4 / 102 (3.92%)		
occurrences (all)	4		
Bone pain			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Musculoskeletal stiffness			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Neck pain			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Tendonitis			

subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Gastroenteritis viral			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Genital herpes			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Herpes simplex			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Infection			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Infective keratitis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	2 / 102 (1.96%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	4 / 102 (3.92%)		
occurrences (all)	5		

Oral herpes			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Pharyngitis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Pulpitis dental			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Rhinitis			
subjects affected / exposed	6 / 102 (5.88%)		
occurrences (all)	6		
Salpingo-oophoritis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	2 / 102 (1.96%)		
occurrences (all)	2		
Skin bacterial infection			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Tonsillitis			
subjects affected / exposed	0 / 102 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	1		
Vulvovaginal candidiasis			
subjects affected / exposed	1 / 102 (0.98%)		
occurrences (all)	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