Clinical trial results:
A Phase I/II randomized observer-blind placebo controlled study to evaluate the safety, reactogenicity and immunogenicity of different dose levels of GSK Biologicals' investigational unadjuvanted RSV Maternal vaccine (GSK3888550A) compared to placebo when administered to healthy non-pregnant women aged 18-45 years

Summary

EudraCT number	2018-001340-62
Trial protocol	FI DE
Global end of trial date	06 September 2019

Results information

Result version number	v2 (current)
This version publication date	22 November 2020
First version publication date	18 April 2020
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	208068

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03674177
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	GSK Response Center, GlaxoSmithKline, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 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	08 November 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	16 April 2019
Global end of trial reached?	Yes
Global end of trial date	06 September 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and reactogenicity of three dose levels (30, 60, 120 µg) of the RSV maternal investigational vaccine administered as a single intramuscular injection, as compared to placebo up to 1 month post vaccination (Day 31).

Protection of trial subjects:

As this was the first time this vaccine was tested in humans, appropriate safety monitoring was planned for this study. The study enrolled in a two-step fashion with a pause in enrollment when the first 60 subjects (approximately 15 subjects per study group) had been vaccinated until the re-view of Day 8 and Day 31 post-vaccination safety data by an unblinded GSK internal Safety Review Committee (iSRC) was completed. The enrollment/vaccination of the remaining subjects started following the favourable outcome of the iSRC safety reviews. In step 1, for the first 30 subjects there was a minimum interval of 60 minutes between vaccinations and vaccination was limited to 10 subjects per day across all sites. In addition to the above, all subjects remained under observation at the vaccination centre for at least 60 minutes after vaccination with appropriate medical treatment readily available. Vaccines were administered by qualified and trained personnel, and only to eligible subjects that have no contraindications to any components of the vaccine. Subjects were followed for about 6 months after vaccination.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 October 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Finland: 61
Country: Number of subjects enrolled	Germany: 211
Country: Number of subjects enrolled	United States: 230
Worldwide total number of subjects	502
EEA total number of subjects	272

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)	502
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 11 centers in 3 countries: 4 in Finland, 5 in Germany and 2 in the USA.

Pre-assignment

Screening details:

Among 579 screened subjects in this study, 77 subjects were screen failure. 502 subjects were enrolled.

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:

This is an observer blind study. In this study, the subject and study site personnel involved in the clinical evaluations of the subjects are blinded while other study personnel may be aware of the treatment assignments.

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV MAT formulation 1 Group

Arm description:

Subjects receive a single dose (30 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm

Arm type	Experimental
Investigational medicinal product name	GSK3888550A RSV Maternal vaccine formulation 1
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose(30 µg) administered intramuscularly at Day 1 in the deltoid region of the non-dominant arm

Arm title	RSV MAT formulation 2 Group

Arm description:

Subjects receive a single dose (60 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm

Arm type	Experimental
Investigational medicinal product name	GSK3888550A RSV Maternal vaccine formulation 2 Group
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose(60 µg) administered intramuscularly at Day 1 in the deltoid region of the non-dominant arm

Arm title	RSV MAT formulation 3 Group

Arm description:

Subjects receive a single dose (120 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm

Arm type	Experimental

Investigational medicinal product name	GSK3888550A RSV Maternal vaccine formulation 3 Group
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Single dose(120 µg) administered intramuscularly at Day 1 in the deltoid region of the non-dominant arm

Arm title	Control Group

Arm description:

Subjects receive a single placebo saline injection at Day 1, intramuscularly into the deltoid region of the non-dominant arm

Arm type	Placebo
Investigational medicinal product name	Placebo (Normal Saline)
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 1 in the deltoid region of the non-dominant arm

Number of subjects in period 1	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group
Started	124	126	126
Completed	122	125	126
Not completed	2	1	0
Lost to follow-up	2	1	-

Number of subjects in period 1	Control Group
Started	126
Completed	124
Not completed	2
Lost to follow-up	2

Baseline characteristics

Reporting groups	
Reporting group title	RSV MAT formulation 1 Group
Reporting group description:	
Subjects receive a single dose (30 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	RSV MAT formulation 2 Group
Reporting group description:	
Subjects receive a single dose (60 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	RSV MAT formulation 3 Group
Reporting group description:	
Subjects receive a single dose (120 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	Control Group
Reporting group description:	
Subjects receive a single placebo saline injection at Day 1, intramuscularly into the deltoid region of the non-dominant arm	

Reporting group values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group
Number of subjects	124	126	126
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	124	126	126
From 65-84 years	0	0	0
85 years and over	0	0	0
Age continuous Units: years			
arithmetic mean	32.5	32.1	31.5
standard deviation	± 7.4	± 7.9	± 7.6
Sex: Female, Male Units:			
Female	124	126	126
Male	0	0	0
Race/Ethnicity, Customized Units: Subjects			
ASIAN	1	1	2
BLACK OR AFRICAN AMERICAN	5	5	4
OTHER	3	0	3
WHITE	115	120	117

Reporting group values	Control Group	Total	
Number of subjects	126	502	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	126	502	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	32.2		
standard deviation	± 7.1	-	
Sex: Female, Male Units:			
Female	126	502	
Male	0	0	
Race/Ethnicity, Customized Units: Subjects			
ASIAN	5	9	
BLACK OR AFRICAN AMERICAN	7	21	
OTHER	0	6	
WHITE	114	466	

End points

End points reporting groups

Reporting group title	RSV MAT formulation 1 Group
Reporting group description:	
Subjects receive a single dose (30 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	RSV MAT formulation 2 Group
Reporting group description:	
Subjects receive a single dose (60 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	RSV MAT formulation 3 Group
Reporting group description:	
Subjects receive a single dose (120 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	Control Group
Reporting group description:	
Subjects receive a single placebo saline injection at Day 1, intramuscularly into the deltoid region of the non-dominant arm	

Primary: Number of Subjects With Any and Grade 3 Solicited Local Adverse events (AE) during a 7-day follow-up period

End point title	Number of Subjects With Any and Grade 3 Solicited Local Adverse events (AE) during a 7-day follow-up period[1]
End point description:	
Assessed solicited local symptoms include pain, redness and swelling, at the injection site. Any = occurrence of the AE regardless of intensity grade. Any Redness and swelling symptom = symptom reported with a surface diameter greater than 20 millimeters. Grade 3 pain = significant pain at rest, pain that prevented normal every day activity. Grade 3 redness/swelling = symptom reported with a surface diameter greater than 100 millimeters. The analysis was performed on the Exposed Set, which included all subjects with the study vaccine administration documented.	
End point type	Primary
End point timeframe:	
During a 7-day follow-up period (i.e., on the day of vaccination and 6 subsequent days)	

Notes:

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

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	125	126	126
Units: Participants				
Pain	59	64	67	20
Grade 3 Pain	1	1	0	0
Redness	8	14	10	1
Grade 3 Redness	0	0	0	0
Swelling	5	7	6	0
Grade 3 Swelling	0	0	1	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects With Any, Grade 3 and related Solicited general Adverse events (AE) during a 7-day follow-up period

End point title	Number of Subjects With Any, Grade 3 and related Solicited general Adverse events (AE) during a 7-day follow-up period[2]

End point description:

Assessed solicited general symptoms include fatigue, gastrointestinal symptoms (nausea, vomiting, diarrhea and/or abdominal pain), headache and fever. Any Fatigue, gastrointestinal symptoms and headache = occurrence of the symptom regardless of intensity grade and relationship. Any Fever = temperature higher than or equal to 38.0 degrees Celsius (°C), or 100.4 degrees Fahrenheit (°F). Grade 3 Fatigue, gastrointestinal symptoms and headache = symptoms that prevented normal activities. Grade 3 Fever = temperature higher than 39.0 degrees Celsius (°C), or 102.2 degrees Fahrenheit (°F). Related fatigue, gastrointestinal symptoms, headache and fever(>38°C) = symptoms assessed by the investigator as related to the vaccination. The analysis was performed on the Exposed Set, which included all subjects with the study vaccine administration documented.

End point type	Primary

End point timeframe:

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

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses as there are no confirmatory analysis

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	125	126	126
Units: Participants				
Any Fatigue	41	49	41	38
Grade 3 Fatigue	3	5	3	4
Related Fatigue	25	34	25	27
Any Gastrointestinal symptoms	30	29	23	27
Grade 3 Gastrointestinal symptoms	2	2	2	1
Related Gastrointestinal symptoms	12	16	13	17
Any Headache	37	51	60	32
Grade 3 Headache	3	6	2	3
Related Headache	17	25	34	17
Any Fever	2	0	4	0
Grade 3 Fever	0	0	0	0
Related Fever	0	0	2	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with any unsolicited AEs during a 30-day follow-up period

End point title	Number of subjects with any unsolicited AEs during a 30-day follow-up period[3]

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 is defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. The analysis was performed on the Exposed Set, which included all vaccinated subjects.

End point type	Primary

End point timeframe:

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

Notes:

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

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	126	126	126
Units: Participants				
Any unsolicited adverse event	45	43	48	44

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with serious adverse events (SAEs) during a 30-day follow-up period

End point title	Number of subjects with serious adverse events (SAEs) during a 30-day follow-up period[4]

End point description:

Assessed SAEs include any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, or results in disability/incapacity, or is a congenital anomaly/birth defect in the offspring of a study subject. The analysis was performed on the Exposed Set, which included all vaccinated subjects.

End point type	Primary

End point timeframe:

From Day 1 (vaccination) up to Day 30 (i.e., on the day of vaccination and 29 subsequent days)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses as there are no confirmatory analysis

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	126	126	126
Units: Participants				
Any serious adverse event	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with hematological laboratory results change with respect to normal laboratory ranges and versus baseline, at Day 8

End point title	Number of subjects with hematological laboratory results change with respect to normal laboratory ranges and versus baseline, at Day 8[5]

End point description:

Assessed hematological laboratory parameters include Eosinophils, Hemoglobin, Lymphocytes, Neutrophils, Platelets, White blood cells (WBC). Hematological abnormalities refer to range indicator at timing, categorized as BELOW, WITHIN or ABOVE normal ranges, and compared to baseline range indicator i.e. BELOW(SCR), WITHIN(SCR) or ABOVE(SCR). [e.g. WBC, BELOW(SCR), BELOW = WBC BELOW normal ranges at baseline versus BELOW normal ranges at Day 8]. The analysis was performed on the Exposed Set, which included all vaccinated subjects with available results for the specified laboratory parameter and time point.

End point type	Primary

End point timeframe:

At Day 8

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: No statistical analyses as there are no confirmatory analysis

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	122	122	125	125
Units: Participants				
Eosinophils, BELOW(SCR), BELOW (N-6,5,7,10)	2	3	3	8
Eosinophils, BELOW(SCR), WITHIN(N-6,5,7,10)	4	2	4	2
Eosinophils, WITHIN(SCR), BELOW(N-112,113,117,113)	3	1	3	3
Eosinophils,WITHIN(SCR),WITHIN (N-112,113,117,113)	108	109	112	110
Eosinophils,WITHIN(SCR),ABOVE(N-112,113,117,113)	1	3	2	0
Eosinophils, ABOVE(SCR), WITHIN (N-4,3,0,2)	2	0	0	1
Eosinophils, ABOVE(SCR), ABOVE (N-4,3,0,2)	2	3	0	1
Hemoglobin, BELOW(SCR), BELOW (N-7,3,1,2)	5	2	1	0

Hemoglobin, BELOW(SCR), WITHIN(N-7,3,1,2)	2	1	0	2
Hemoglobin,WITHIN(SCR), BELOW (N-115,117,122,122)	2	2	1	5
Hemoglobin, WITHIN(SCR), WITHIN(N-115,117,122,122)	112	115	120	117
Hemoglobin,WITHIN(SCR),ABOVE (N-115,117,122,122)	1	0	1	0
Hemoglobin,ABOVE(SCR),WITHIN (N-0,2,2,1)	0	1	2	0
Hemoglobin,ABOVE(SCR),ABOVE (N-0,2,2,1)	0	1	0	1
Lymphocytes, BELOW(SCR), WITHIN (N-0,2,2,0)	0	2	2	0
Lymphocytes,WITHIN(SCR),BELOW (N-120,118,122,124)	1	1	1	1
Lymphocytes,WITHIN(SCR),WITHIN (N-120,118,122,124)	119	116	119	121
Lymphocytes,WITHIN(SCR),ABOVE (N-120,118,122,124)	0	1	2	2
Lymphocytes, ABOVE(SCR), WITHIN (N-2,1,0,1)	1	0	0	0
Lymphocytes, ABOVE(SCR), ABOVE (N-2,1,0,1)	1	1	0	1
Neutrophils, BELOW(SCR), WITHIN (N-1,1,0,1)	1	1	0	1
Neutrophils,WITHIN(SCR),BELOW (N-120,119,120,120)	2	4	2	1
Neutrophils,WITHIN(SCR),WITHIN (N-120,119,120,120)	117	111	117	118
Neutrophils,WITHIN(SCR),ABOVE (N-120,119,120,120)	1	4	1	1
Neutrophils, ABOVE(SCR), WITHIN (N-1,1,4,4)	1	1	1	3
Neutrophils, ABOVE(SCR), ABOVE (N-1,1,4,4)	0	0	3	1
Platelets, BELOW(SCR), BELOW (N-0,0,1,2)	0	0	0	1
Platelets, BELOW(SCR), WITHIN (N-0,0,1,2)	0	0	1	1
Platelets, WITHIN(SCR), BELOW (N-118,117,119,116)	1	0	0	0
Platelets, WITHIN(SCR), WITHIN (N-118,117,119,116)	116	112	115	114
Platelets, WITHIN(SCR), ABOVE (N-118,117,119,116)	1	5	4	2
Platelets, ABOVE(SCR), WITHIN (N-4,5,5,7)	3	2	3	3
Platelets, ABOVE(SCR), ABOVE (N-4,5,5,7)	1	3	2	4
WBC, BELOW(SCR), BELOW (N-3,2,5,5)	0	1	1	5
WBC, BELOW(SCR), WITHIN (N-3,2,5,5)	3	1	4	0
WBC, WITHIN(SCR), BELOW (N-118,117,116,115)	5	4	5	0
WBC, WITHIN(SCR), WITHIN (N-118,117,116,115)	111	108	108	115
WBC, WITHIN(SCR), ABOVE (N-118,117,116,115)	2	5	3	0
WBC, ABOVE(SCR), WITHIN (N-1,3,4,5)	0	1	1	5
WBC, ABOVE(SCR), ABOVE (N-1,3,4,5)	1	2	3	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with hematological laboratory results change with respect to normal laboratory ranges and versus baseline, at Day 31

End point title	Number of subjects with hematological laboratory results change with respect to normal laboratory ranges and versus baseline, at Day 31[6]

End point description:

Assessed hematological laboratory parameters include Eosinophils, Hemoglobin, Lymphocytes, Neutrophils, Platelets, White blood cells (WBC). Hematological abnormalities refer to range indicator at timing, categorized as BELOW, WITHIN or ABOVE normal ranges, and compared to baseline range indicator i.e. BELOW(SCR), WITHIN(SCR) or ABOVE(SCR) [e.g. WBC, BELOW(SCR), BELOW = WBC BELOW normal ranges at baseline versus BELOW normal ranges at Day 31]. The analysis was performed on the Exposed Set, which included all vaccinated subjects with available results for the specified laboratory parameter and time point.

End point type	Primary

End point timeframe:

At Day 31

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: No statistical analyses as there are no confirmatory analysis

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	121	124	125	125
Units: Participants				
Eosinophils, BELOW(SCR), BELOW (N-7,6,8,11)	3	3	6	8
Eosinophils, BELOW(SCR), WITHIN (N-7,6,8,11)	4	3	2	3
Eosinophils,WITHIN(SCR),BELOW (N-110,115,117,112)	4	2	1	1
Eosinophils,WITHIN(SCR),WITHIN(N-110,115,117,112)	105	112	115	110
Eosinophils,WITHIN(SCR),ABOVE (N-110,115,117,112)	1	1	1	1
Eosinophils, ABOVE(SCR), WITHIN (N-4,3,0,2)	2	1	0	1
Eosinophils, ABOVE(SCR), ABOVE (N-4,3,0,2)	2	2	0	1
Hemoglobin, BELOW(SCR), BELOW (N-7,3,1,2)	6	1	1	2
Hemoglobin, BELOW(SCR), WITHIN (N-7,3,1,2)	1	2	0	0
Hemoglobin, WITHIN(SCR), BELOW (N-114,118,122,122)	2	4	1	3

Hemoglobin, WITHIN(SCR), WITHIN(N-114,118,122,122)	112	114	121	119
Hemoglobin, ABOVE(SCR), WITHIN (N-0,3,2,1)	0	2	1	0
Hemoglobin, ABOVE(SCR), ABOVE (N-0,3,2,1)	0	1	1	1
Lymphocytes, BELOW(SCR), BELOW (N-0,2,2,0)	0	1	0	0
Lymphocytes, BELOW(SCR), WITHIN (N-0,2,2,0)	0	1	2	0
Lymphocytes, WITHIN(SCR), BELOW(N-119,120,123,124)	0	1	3	2
Lymphocytes,WITHIN(SCR),WITHIN(N-119,120,123,124)	119	119	119	119
Lymphocytes,WITHIN(SCR),ABOVE (N-119,120,123,124)	0	0	1	3
Lymphocytes, ABOVE(SCR), WITHIN (N-2,2,0,1)	2	1	0	0
Lymphocytes, ABOVE(SCR), ABOVE (N-2,2,0,1)	0	1	0	1
Neutrophils, BELOW(SCR), BELOW (N-1,1,0,1)	1	0	0	0
Neutrophils,BELOW(SCR),WITHIN(N-1,1,0,1)	0	1	0	1
Neutrophils,WITHIN(SCR),BELOW(N-119,122,121,120)	2	2	3	1
Neutrophils,WITHIN(SCR),WITHIN (N-119,122,121,120)	116	117	114	116
Neutrophils,WITHIN(SCR),ABOVE (N-119,122,121,120)	1	3	4	3
Neutrophils, ABOVE(SCR), WITHIN (N-1,1,4,4)	1	0	4	4
Neutrophils, ABOVE(SCR), ABOVE (N-1,1,4,4)	0	1	0	0
Platelets, BELOW(SCR), BELOW (N-0,0,1,2)	0	0	0	1
Platelets, BELOW(SCR), WITHIN (N-0,0,1,2)	0	0	1	1
Platelets, WITHIN(SCR), BELOW (N-117,119,119,116)	0	0	2	0
Platelets, WITHIN(SCR), WITHIN (N-117,119,119,116)	115	115	111	113
Platelets, WITHIN(SCR), ABOVE (N-117,119,119,116)	2	4	6	3
Platelets, ABOVE(SCR), WITHIN (N-4,5,5,7)	3	1	3	2
Platelets, ABOVE(SCR), ABOVE (N-4,5,5,7)	1	4	2	5
WBC, BELOW(SCR), BELOW (N-3,2,4,5)	2	1	2	4
WBC, BELOW(SCR), WITHIN (N-3,2,4,5)	1	1	2	1
WBC, WITHIN(SCR), BELOW (N-117,119,117,115)	3	5	9	1
WBC, WITHIN(SCR), WITHIN (N-117,119,117,115)	109	107	105	110
WBC, WITHIN(SCR), ABOVE (N-117,119,117,115)	5	7	3	4
WBC, ABOVE(SCR), WITHIN (N-1,3,4,5)	1	0	4	5
WBC, ABOVE(SCR), ABOVE (N-1,3,4,5)	0	3	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with biochemical laboratory results change with respect to normal laboratory ranges and versus baseline, at Day 8

End point title	Number of subjects with biochemical laboratory results change with respect to normal laboratory ranges and versus baseline, at Day 8[7]

End point description:

Assessed biochemical laboratory parameters include alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN) and creatinine. Biochemical abnormalities refer to range indicator at timing, categorized as BELOW, WITHIN or ABOVE normal ranges, and compared to baseline range indicator i.e. BELOW(SCR), WITHIN(SCR) or ABOVE(SCR)[e.g. ALT, BELOW(SCR), BELOW = ALT BELOW normal ranges at baseline versus BELOW normal ranges at Day 8]. The analysis was performed on the Exposed Set, which included all vaccinated subjects with available results for the specified laboratory parameter and time point.

End point type	Primary

End point timeframe:

At Day 8

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: No statistical analyses as there are no confirmatory analysis

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123	124	126	126
Units: Participants				
ALT, BELOW(SCR), WITHIN (N-0,2,0,0)	0	2	0	0
ALT, WITHIN(SCR), WITHIN (N-115,116,123,115)	114	109	120	111
ALT, WITHIN(SCR), ABOVE (N-115,116,123,115)	1	7	3	4
ALT, ABOVE(SCR), WITHIN (N-8,6,3,10)	3	6	3	3
ALT, ABOVE(SCR), ABOVE (N-8,6,3,10)	5	0	0	7
AST, BELOW(SCR), WITHIN (N-1,1,2,0)	1	1	2	0
AST, WITHIN(SCR), BELOW (N-119,122,120,118)	0	1	0	0
AST, WITHIN(SCR), WITHIN (N-119,122,120,118)	116	115	116	116
AST, WITHIN(SCR), ABOVE (N-119,122,120,118)	3	6	4	2
AST, ABOVE(SCR), WITHIN (N-3,1,4,7)	3	1	3	6
AST, ABOVE(SCR), ABOVE (N-3,1,4,7)	0	0	1	1
BUN, BELOW(SCR), BELOW (N-4,4,7,1)	3	2	3	1
BUN, BELOW(SCR), WITHIN (N-4,4,7,1)	1	2	4	0

BUN, WITHIN(SCR), BELOW (N-116,119,115,123)	1	2	2	1
BUN, WITHIN(SCR), WITHIN (N-116,119,115,123)	113	115	113	121
BUN, WITHIN(SCR), ABOVE (N-116,119,115,123)	2	2	0	1
BUN, ABOVE(SCR), WITHIN (N-3,1,3,2)	2	0	3	2
BUN, ABOVE(SCR), ABOVE (N-3,1,3,2)	1	1	0	0
Creatinine, BELOW(SCR), BELOW (N-2,3,4,4)	0	1	1	4
Creatinine, BELOW(SCR), WITHIN (N-2,3,4,4)	2	2	3	0
Creatinine, WITHIN(SCR), BELOW (N-119,121,121,121)	1	0	1	3
Creatinine,WITHIN(SCR),WITHIN(N-119,121,121,121)	117	118	119	118
Creatinine, WITHIN(SCR), ABOVE (N-119,121,121,121)	1	3	1	0
Creatinine, ABOVE(SCR), WITHIN (N-2,0,1,1)	2	0	1	0
Creatinine, ABOVE(SCR), ABOVE (N-2,0,1,1)	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with biochemical laboratory results change with respect to normal laboratory ranges and versus baseline, at Day 31

End point title	Number of subjects with biochemical laboratory results change with respect to normal laboratory ranges and versus baseline, at Day 31[8]

End point description:

Assessed biochemical laboratory parameters include alanine aminotransferase (ALT), aspartate aminotransferase (AST), creatinine and blood urea nitrogen (BUN). Biochemical abnormalities refer to range indicator at timing, categorized as BELOW, WITHIN or ABOVE normal ranges, and compared to baseline range indicator i.e. BELOW(SCR), WITHIN(SCR) or ABOVE(SCR) [e.g. ALT, BELOW(SCR), BELOW = ALT BELOW normal ranges at baseline versus BELOW normal ranges at Day 31]. The analysis was performed on the Exposed Set, which included all vaccinated subjects with available results for the specified laboratory parameter and time point.

End point type	Primary

End point timeframe:

At Day 31

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses as there are no confirmatory analysis

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123	124	126	126
Units: Participants				
ALT, BELOW(SCR), BELOW (N-0,2,0,0)	0	1	0	0
ALT, BELOW(SCR), WITHIN (N-0,2,0,0)	0	1	0	0

ALT, WITHIN(SCR), BELOW (N-115,116,123,116)	0	0	1	0
ALT, WITHIN(SCR), WITHIN (N-115,116,123,116)	112	113	121	110
ALT, WITHIN(SCR), ABOVE (N-115,116,123,116)	3	3	1	6
ALT, ABOVE(SCR), WITHIN (N-8,6,3,10)	4	5	3	6
ALT, ABOVE(SCR), ABOVE (N-8,6,3,10)	4	1	0	4
AST, BELOW(SCR), WITHIN (N-1,1,2,0)	1	1	2	0
AST, WITHIN(SCR), BELOW (N-119,122,120,119)	0	0	0	1
AST, WITHIN(SCR), WITHIN (N-119,122,120,119)	115	118	120	114
AST, WITHIN(SCR), ABOVE (N-119,122,120,119)	4	4	0	4
AST, ABOVE(SCR), WITHIN (N-3,1,4,7)	3	1	3	6
AST, ABOVE(SCR), ABOVE (N-3,1,4,7)	0	0	1	1
BUN, BELOW(SCR), BELOW (N-4,4,7,1)	2	2	2	1
BUN, BELOW(SCR), WITHIN (N-4,4,7,1)	2	2	5	0
BUN, WITHIN(SCR), BELOW (N-116,119,116,123)	2	2	0	2
BUN, WITHIN(SCR), WITHIN (N-116,119,116,123)	113	117	115	120
BUN, WITHIN(SCR), ABOVE (N-116,119,116,123)	1	0	1	1
BUN, ABOVE(SCR), WITHIN (N-3,1,3,2)	3	0	3	2
BUN, ABOVE(SCR), ABOVE (N-3,1,3,2)	0	1	0	0
Creatinine, BELOW(SCR), BELOW (N-2,3,4,4)	0	0	0	3
Creatinine, BELOW(SCR), WITHIN (N-2,3,4,4)	2	3	4	1
Creatinine, WITHIN(SCR), BELOW (N-119,121,121,121)	0	1	0	2
Creatinine,WITHIN(SCR),WITHIN (N-119,121,121,121)	118	116	117	116
Creatinine, WITHIN(SCR), ABOVE (N-119,121,121,121)	1	4	4	3
Creatinine, ABOVE(SCR), WITHIN (N-2,0,1,1)	1	0	1	0
Creatinine, ABOVE(SCR), ABOVE (N-2,0,1,1)	1	0	0	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with hematological laboratory results versus baseline, by maximum grading, at Day 8

End point title	Number of subjects with hematological laboratory results versus baseline, by maximum grading, at Day 8[9]

End point description:

Assessed hematological laboratory parameters include Eosinophils, Hemoglobin, Lymphocytes Decrease(Lym Dec), Neutrophils Decrease(Neu Dec), Platelets Decrease(Dec), WBC Decrease(Dec) and WBC Increase(Inc), as graded by the Food and Drug Administration [FDA] Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials. Assessed grades at specified time point, are Grade 1 = mild, Grade 2 = moderate, Grade

and Grade 4 = life threatening, as compared to the baseline status of the same parameter, at baseline [e.g. WBC decrease-Grade 1(SCR)-Grade 1 = WBC decrease Grade 1 at baseline versus Grade 1 at Day 8]. "Any" corresponding to any grade and "Grade 0" to normal ranges. The analysis was performed on the Exposed Set, which included all vaccinated subjects with available results for the specified laboratory parameter and time point.

End point type	Primary

End point timeframe:

At Day 8

Notes:

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

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	122	122	125	125
Units: Participants				
Eosinophils, Any(SCR), GRADE 0(N-122,121,124,125)	121	120	124	125
Eosinophils, Any(SCR), GRADE 1(N-122,121,124,125)	1	0	0	0
Eosinophils, Any(SCR), GRADE 2(N-122,121,124,125)	0	1	0	0
Eosinophils,Grade0(SCR),GRADE 0(N-120,120,124,123)	119	120	124	123
Eosinophils,Grade0(SCR),GRADE 1(N-120,120,124,123)	1	0	0	0
Eosinophils,Grade1(SCR),GRADE 0(N=2,1,0,2)	2	0	0	2
Eosinophils, Grade 1(SCR), GRADE 2 (N-2,1,0,2)	0	1	0	0
Hemoglobin, Any(SCR), GRADE 0 (N-122,122,125,125)	110	111	114	110
Hemoglobin, Any(SCR), GRADE 1 (N-122,122,125,125)	11	9	10	15
Hemoglobin, Any(SCR), GRADE 2 (N-122,122,125,125)	1	2	1	0
Hemoglobin,Grade 0(SCR),GRADE 0(N-110,111,115,116)	106	107	110	106
Hemoglobin,Grade 0(SCR),GRADE 1(N-110,111,115,116)	4	4	5	10
Hemoglobin, Grade 1(SCR), GRADE 0 (N-11,11,10,9)	4	4	4	4
Hemoglobin, Grade 1(SCR), GRADE 1 (N-11,11,10,9)	7	5	5	5
Hemoglobin, Grade 1(SCR), GRADE 2 (N-11,11,10,9)	0	2	1	0
Hemoglobin, Grade 2(SCR), GRADE 2 (N-1,0,0,0)	1	0	0	0
Lym Dec, Any(SCR), GRADE 0 (N-122,121,124,125)	120	118	122	122
Lym Dec, Any(SCR), GRADE 1 (N-122,121,124,125)	1	2	2	3
Lym Dec, Any(SCR), GRADE 2 (N-122,121,124,125)	1	1	0	0
Lym Dec, Grade 0(SCR), GRADE 0 (N-122,119,120,120)	120	117	118	120
Lym Dec, Grade 0(SCR), GRADE 1 (N-122,119,120,120)	1	1	2	0

Lym Dec, Grade 0(SCR), GRADE 2 (N-122,119,120,120)	1	1	0	0
Lym Dec, Grade 1(SCR), GRADE 0 (N-0,2,3,5)	0	1	3	2
Lym Dec, Grade 1(SCR), GRADE 1 (N-0,2,3,5)	0	1	0	3
Lym Dec, Grade 2(SCR), GRADE 0 (N-0,0,1,0)	0	0	1	0
Neu Dec, Any(SCR), GRADE 0 (N-122,121,124,125)	112	113	116	118
Neu Dec, Any(SCR), GRADE 1 (N-122,121,124,125)	10	5	8	6
Neu Dec, Any(SCR), GRADE 2 (N-122,121,124,125)	0	3	0	1
Neu Dec, Grade 0(SCR), GRADE 0 (N-117,115,119,119)	109	109	111	115
Neu Dec, Grade 0(SCR), GRADE 1 (N-117,115,119,119)	8	4	8	4
Neu Dec, Grade 0(SCR), GRADE 2 (N-117,115,119,119)	0	2	0	0
Neu Dec, Grade 1(SCR), GRADE 0 (N-4,6,5,6)	3	4	5	3
Neu Dec, Grade 1(SCR), GRADE 1 (N-4,6,5,6)	1	1	0	2
Neu Dec, Grade 1(SCR), GRADE 2 (N-4,6,5,6)	0	1	0	1
Neu Dec, Grade 2(SCR), GRADE 1 (N-1,0,0,0)	1	0	0	0
Platelet Dec,Any(SCR),GRADE 0(N-122,122,125,125)	121	122	125	125
Platelet Dec,Any(SCR),GRADE1(N-122,122,125,125)	1	0	0	0
Platelet Dec,Grade0(SCR),GRADE0(N-122,122,125,123)	121	122	125	123
Platelet Dec,Grade0(SCR),GRADE1(N-122,122,125,123)	1	0	0	0
Platelet Dec, Grade 1(SCR), GRADE 0 (N-0,0,0,2)	0	0	0	2
WBC Dec, Any(SCR), GRADE 0 (N-122,122,125,125)	121	119	125	124
WBC Dec, Any(SCR), GRADE 1 (N-122,122,125,125)	1	3	0	1
WBC Dec, Grade 0(SCR), GRADE 0 (N-121,121,124,121)	120	118	124	120
WBC Dec, Grade 0(SCR), GRADE 1 (N-121,121,124,121)	1	3	0	1
WBC Dec, Grade 1(SCR), GRADE 0 (N-1,1,1,4)	1	1	1	4
WBC Inc, Any(SCR), GRADE 0 (N-122,122,125,125)	119	118	121	125
WBC Inc, Any(SCR), GRADE 1 (N-122,122,125,125)	3	3	4	0
WBC Inc, Any(SCR), GRADE 2 (N-122,122,125,125)	0	1	0	0
WBC Inc, Grade 0(SCR), GRADE 0 (N-119,118,121,122)	118	116	120	122
WBC Inc, Grade 0(SCR), GRADE 1 (N-119,118,121,122)	1	2	1	0
WBC Inc, Grade 1(SCR), GRADE 0 (N-3,4,4,3)	1	2	1	3
WBC Inc, Grade 1(SCR), GRADE 1 (N-3,4,4,3)	2	1	3	0

WBC Inc, Grade 1(SCR), GRADE 2 (N-3,4,4,3)	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with hematological laboratory results versus baseline, by maximum grading, at Day 31

End point title	Number of subjects with hematological laboratory results versus baseline, by maximum grading, at Day 31[10]

End point description:

Assessed hematological laboratory parameters include Eosinophils, Hemoglobin, Lymphocytes Decrease(Lym Dec), Neutrophils Decrease(Neu Dec), Platelets Decrease(Dec), WBC Decrease(Dec) and WBC Increase(Inc), as graded by the Food and Drug Administration [FDA] Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials. Assessed grades at specified time point, are Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe and Grade 4 = life threatening, as compared to the baseline status of the same parameter, at baseline [e.g. WBC decrease-Grade 1(SCR)-Grade 1 = WBC decrease Grade 1 at baseline versus Grade 1 at Day 31]. "Any" corresponding to any grade and "Grade 0" to normal ranges. The analysis was performed on the Exposed Set, which included all vaccinated subjects with available results for the specified laboratory parameter and time point.

End point type	Primary

End point timeframe:

At Day 31

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses as there are no confirmatory analysis

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	121	124	125	125
Units: Participants				
Eosinophils,Any(SCR),GRADE 0 (N-121,124,125,125)	118	122	125	125
Eosinophils,Any(SCR),GRADE 1 (N-121,124,125,125)	3	2	0	0
Eosinophils,Grade 0(SCR),GRADE0(N-119,123,125,123)	117	122	125	123
Eosinophils,Grade 0(SCR),GRADE1(N-119,123,125,123)	2	1	0	0
Eosinophils,Grade 1(SCR),GRADE 0(N-2,1,0,2)	1	0	0	2
Eosinophils,Grade 1(SCR),GRADE 1(N-2,1,0,2)	1	1	0	0
Hemoglobin,Any(SCR),GRADE 0 (N-121,124,125,125)	108	115	112	114
Hemoglobin,Any(SCR),GRADE 1 (N-121,124,125,125)	11	7	13	8
Hemoglobin,Any(SCR),GRADE 2 (N-121,124,125,125)	2	2	0	3

Hemoglobin,Grade 0(SCR),GRADE 0(N-110,113,115,116)	106	112	109	111
Hemoglobin,Grade 0(SCR),GRADE 1(N-110,113,115,116)	4	1	6	3
Hemoglobin,Grade 0(SCR),GRADE 2(N-110,113,115,116)	0	0	0	2
Hemoglobin,Grade 1(SCR),GRADE 0(N-10,11,10,9)	2	3	3	3
Hemoglobin,Grade 1(SCR),GRADE 1(N-10,11,10,9)	7	6	7	5
Hemoglobin,Grade 1(SCR),GRADE 2(N-10,11,10,9)	1	2	0	1
Hemoglobin,Grade 2(SCR),GRADE 2(N-1,0,0,0)	1	0	0	0
Lym Dec,Any(SCR),GRADE 0(N-121,124,125,125)	119	119	121	120
Lym Dec, Any(SCR), GRADE 1(N-121,124,125,125)	2	5	4	4
Lym Dec, Any(SCR), GRADE 2(N-121,124,125,125)	0	0	0	1
Lym Dec, Grade 0(SCR), GRADE 0(N-121,122,121,120)	119	118	117	117
Lym Dec, Grade 0(SCR), GRADE 1(N-121,122,121,120)	2	4	4	3
Lym Dec, Grade 1(SCR), GRADE 0(N-0,2,3,5)	0	1	3	3
Lym Dec, Grade 1(SCR), GRADE 1(N-0,2,3,5)	0	1	0	1
Lym Dec, Grade 1(SCR), GRADE 2(N-0,2,3,5)	0	0	0	1
Lym Dec, Grade 2(SCR), GRADE 0(N-0,0,1,0)	0	0	1	0
Neu Dec, Any(SCR), GRADE 0(N-121,124,125,125)	111	115	114	116
Neu Dec, Any(SCR), GRADE 1(N-121,124,125,125)	8	7	10	8
Neu Dec, Any(SCR), GRADE 2(N-121,124,125,125)	1	2	1	1
Neu Dec, Any(SCR), GRADE 3(N-121,124,125,125)	1	0	0	0
Neu Dec, Grade 0(SCR), GRADE 0(N-117,118,120,119)	109	112	109	114
Neu Dec, Grade 0(SCR), GRADE 1(N-117,118,120,119)	7	5	10	4
Neu Dec,Grade 0(SCR), GRADE 2(N-117,118,120,119)	0	1	1	1
Neu Dec,Grade 0(SCR), GRADE 3(N-117,118,120,119)	1	0	0	0
Neu Dec,Grade 1(SCR), GRADE 0(N-3,6,5,6)	2	3	5	2
Neu Dec,Grade 1(SCR), GRADE 1(N-3,6,5,6)	1	2	0	4
Neu Dec,Grade 1(SCR), GRADE 2(N-3,6,5,6)	0	1	0	0
Neu Dec,Grade 2(SCR), GRADE 2(N-1,0,0,0)	1	0	0	0
Platelet Dec,Any(SCR),GRADE0(N-121,124,125,125)	121	124	125	125
Platelet Dec,Grade0(SCR),GRADE0(N-121,124,125,123)	121	124	125	123
Platelet Dec,Grade 1(SCR),GRADE0(N-0,0,0,2)	0	0	0	2

WBC Dec, Any(SCR), GRADE 0(N-121,124,125,125)	119	122	121	123
WBC Dec, Any(SCR), GRADE 1(N-121,124,125,125)	2	2	4	2
WBC Dec, Grade 0(SCR), GRADE 0(N-120,123,124,121)	119	121	120	120
WBC Dec, Grade 0(SCR), GRADE 1(N-120,123,124,121)	1	2	4	1
WBC Dec, Grade 1(SCR), GRADE 0(N-1,1,1,4)	0	1	1	3
WBC Dec, Grade 1(SCR), GRADE 1(N-1,1,1,4)	1	0	0	1
WBC Inc, Any(SCR), GRADE 0(N-121,124,125,125)	120	116	122	122
WBC Inc, Any(SCR), GRADE 1(N-121,124,125,125)	1	8	3	3
WBC Inc, Grade 0(SCR), GRADE 0(N-118,120,121,122)	118	115	118	119
WBC Inc, Grade 0(SCR), GRADE 1(N-118,120,121,122)	0	5	3	3
WBC Inc, Grade 1(SCR), GRADE 0(N-3,4,4,3)	2	1	4	3
WBC Inc, Grade 1(SCR), GRADE 1(N-3,4,4,3)	1	3	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with biochemical laboratory results versus baseline, by maximum grading, at Day 8

End point title	Number of subjects with biochemical laboratory results versus baseline, by maximum grading, at Day 8[11]

End point description:

Assessed biochemical laboratory parameters include alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN) and creatinine, as graded by the Food and Drug Administration [FDA] Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials. Assessed grades at specified time point, are Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe and Grade 4 = life threatening, as compared to the baseline status of the same parameter, at baseline [e.g. ALT-Grade 1(SCR)-Grade 1 = ALT Grade 1 at baseline versus Grade 1 at Day 8]. "Any" corresponding to any grade and "Grade 0" to normal ranges. Increase By Factor = IBF The analysis was performed on the Exposed Set, which included all vaccinated subjects with available results for the specified laboratory parameter and time point.

End point type	Primary

End point timeframe:

At Day 8

Notes:

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

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123	124	126	126
Units: Participants				
ALT-IBF, Any(SCR), GRADE 0(N-123,124,126,125)	118	119	124	117
ALT-IBF, Any(SCR), GRADE 1(N-123,124,126,125)	5	3	1	7
ALT-IBF, Any(SCR), GRADE 2(N-123,124,126,125)	0	1	1	0
ALT-IBF, Any(SCR), GRADE 3(N-123,124,126,125)	0	1	0	1
ALT-IBF, Grade 0(SCR), GRADE 0(N-116,120,123,116)	115	115	121	114
ALT-IBF, Grade 0(SCR), GRADE 1(N-116,120,123,116)	1	3	1	2
ALT-IBF, Grade 0(SCR), GRADE 2(N-116,120,123,116)	0	1	1	0
ALT-IBF, Grade 0(SCR), GRADE 3(N-116,120,123,116)	0	1	0	0
ALT-IBF, Grade 1(SCR), GRADE 0(N-6,4,3,9)	3	4	3	3
ALT-IBF, Grade 1(SCR), GRADE 1(N-6,4,3,9)	3	0	0	5
ALT-IBF, Grade 1(SCR), GRADE 3(N-6,4,3,9)	0	0	0	1
ALT-IBF, Grade 2(SCR), GRADE 1(N-1,0,0,0)	1	0	0	0
AST-IBF, Any(SCR), GRADE 0(N-123,124,126,125)	123	120	124	122
AST-IBF, Any(SCR), GRADE 1(N-123,124,126,125)	0	3	2	3
AST-IBF, Any(SCR), GRADE 3(N-123,124,126,125)	0	1	0	0
AST-IBF, Grade 0(SCR), GRADE 0(N-120,123,125,121)	120	119	124	119
AST-IBF, Grade 0(SCR), GRADE 1(N-120,123,125,121)	0	3	1	2
AST-IBF, Grade 0(SCR), GRADE 3(N-120,123,125,121)	0	1	0	0
AST-IBF, Grade 1(SCR), GRADE 0(N-3,1,1,4)	3	1	0	3
AST-IBF, Grade 1(SCR), GRADE 1(N-3,1,1,4)	0	0	1	1
BUN, Any(SCR), GRADE 0(N-123,124,125,126)	122	123	124	125
BUN, Any(SCR), GRADE 1(N-123,124,125,126)	1	1	1	0
BUN, Any(SCR), GRADE 2(N-123,124,125,126)	0	0	0	1
BUN, Grade 0(SCR), GRADE 0(N-123,124,124,126)	122	123	123	124
BUN, Grade 0(SCR), GRADE 1(N-123,124,124,126)	1	1	1	0
BUN, Grade 0(SCR), GRADE 2(N-123,124,124,126)	0	0	0	1
BUN, Grade 1(SCR), GRADE 0(N-0,0,1,0)	0	0	1	0
BUN, Grade 2(SCR), GRADE 0(N-0,0,0,1)	0	0	0	1

Creatinine, Any(SCR), GRADE 0 (N-123,124,126,126)	122	124	126	126
Creatinine,Any(SCR), GRADE 3(N-123,124,126,126)	1	0	0	0
Creatinine,Grade 0(SCR),GRADE 0(N-123,124,126,126)	122	124	126	126
Creatinine,Grade 0(SCR),GRADE 3(N-123,124,126,126)	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of subjects with biochemical laboratory results versus baseline, by maximum grading, at Day 31

End point title	Number of subjects with biochemical laboratory results versus baseline, by maximum grading, at Day 31[12]

End point description:

Assessed biochemical laboratory parameters include alanine aminotransferase (ALT), aspartate aminotransferase (AST), blood urea nitrogen (BUN) and creatinine, as graded by the Food and Drug Administration [FDA] Guidance for Industry "Toxicity Grading Scale for Healthy Adult and Adolescent Volunteers Enrolled in Preventive Vaccine Clinical Trials. Assessed grades at specified time point, are Grade 1 = mild, Grade 2 = moderate, Grade 3 = severe and Grade 4 = life threatening, as compared to the baseline status of the same parameter, at baseline [e.g. ALT-Grade 1(SCR)-Grade 1 = ALT Grade 1 at baseline versus Grade 1 at Day 31]. "Any" corresponding to any grade and "Grade 0" to normal ranges. Increase By Factor = IBF The analysis was performed on the Exposed Set, which included all vaccinated subjects with available results for the specified laboratory parameter and time point.

End point type	Primary

End point timeframe:

At Day 31

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No statistical analyses as there are no confirmatory analysis

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123	124	126	126
Units: Participants				
ALT-IBF, Any(SCR), GRADE 0(N-123,124,126,126)	117	121	125	118
ALT-IBF, Any(SCR), GRADE 1(N-123,124,126,126)	6	3	1	6
ALT-IBF, Any(SCR), GRADE 2(N-123,124,126,126)	0	0	0	2
ALT-IBF, Grade 0(SCR), GRADE 0(N-116,120,123,117)	113	117	122	112
ALT-IBF, Grade 0(SCR), GRADE 1(N-116,120,123,117)	3	3	1	4
ALT-IBF, Grade 0(SCR), GRADE 2(N-116,120,123,117)	0	0	0	1
ALT-IBF, Grade 1(SCR), GRADE 0(N-6,4,3,9)	4	4	3	6
ALT-IBF, Grade 1(SCR), GRADE 1(N-6,4,3,9)	2	0	0	2

ALT-IBF, Grade 1(SCR), GRADE 2(N-6,4,3,9)	0	0	0	1
ALT-IBF, Grade 2(SCR), GRADE 1(N-1,0,0,0)	1	0	0	0
AST-IBF, Any(SCR), GRADE 0(N-123,124,126,126)	121	122	125	121
AST-IBF, Any(SCR), GRADE 1(N-123,124,126,126)	2	2	1	3
AST-IBF, Any(SCR), GRADE 2(N-123,124,126,126)	0	0	0	2
AST-IBF, Grade 0(SCR), GRADE 0(N-120,123,125,122)	118	121	125	118
AST-IBF, Grade 0(SCR), GRADE 1(N-120,123,125,122)	2	2	0	3
AST-IBF, Grade 0(SCR), GRADE 2(N-120,123,125,122)	0	0	0	1
AST-IBF, Grade 1(SCR), GRADE 0(N-3,1,1,4)	3	1	0	3
AST-IBF, Grade 1(SCR), GRADE 1(N-3,1,1,4)	0	0	1	0
AST-IBF, Grade 1(SCR), GRADE 2(N-3,1,1,4)	0	0	0	1
BUN, Any(SCR), GRADE 0(N-123,124,126,126)	123	123	126	125
BUN, Any(SCR), GRADE 1(N-123,124,126,126)	0	0	0	1
BUN, Any(SCR), GRADE 2(N-123,124,126,126)	0	1	0	0
BUN, Grade 0(SCR), GRADE 0(N-123,124,125,125)	123	123	125	124
BUN, Grade 0(SCR), GRADE 1(N-123,124,125,125)	0	0	0	1
BUN, Grade 0(SCR), GRADE 2(N-123,124,125,125)	0	1	0	0
BUN, Grade 1(SCR), GRADE 0(N-0,0,1,0)	0	0	1	0
BUN, Grade 2(SCR), GRADE 0(N-0,0,0,1)	0	0	0	1
Creatinine,Any(SCR),GRADE 0(N-123,124,126,126)	123	124	126	126
Creatinine,Grade 0(SCR),GRADE 0(N-123,124,126,126)	123	124	126	126

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with SAEs

End point title	Number of subjects with SAEs

End point description:

Assessed SAEs include any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, or results in disability/incapacity, or is a congenital anomaly/birth defect in the offspring of a study subject. The analysis was performed on the Exposed Set, which included all vaccinated subjects.

End point type	Secondary

End point timeframe:

From Day 1 (vaccination) up to Day 91 and up to Day 181

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	124	126	126	126
Units: Participants				
SAE - Day 91	0	0	1	1
SAE - Day 181	0	0	1	2

Statistical analyses

No statistical analyses for this end point

Secondary: Neutralizing antibody (Nab) titers against RSV serotype A

End point title	Neutralizing antibody (Nab) titers against RSV serotype A

End point description:

Anti RSV-A neutralizing antibody titers are given as geometric mean titers (GMTs) and expressed as Estimated Dose: serum dilution giving a 60% reduction of the signal compared to a control without serum (ED60), calculated on subjects with anti-RSV-A neutralizing antibody titer equal to or above the assay cut-off 18 ED60.
The analysis was performed on the Per-protocol set which included all vaccinated subjects, meeting all protocol requirements and for whom immunogenicity results were available for the specified assay at the corresponding time-point.

End point type	Secondary

End point timeframe:

At pre-vaccination at screening (PRE), 7 days post vaccination (Day 8), 30 days post vaccination (Day 31), 60 days post vaccination (Day 61) and 90 days post vaccination (Day 91)

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123	125	126	126
Units: Titers				
geometric mean (confidence interval 95%)				
PRE (N-123,125,126,126)	851.1 (732.88 to 988.3)	921.6 (795.52 to 1067.64)	868.8 (754.18 to 1000.78)	746.2 (639.96 to 870.02)
Day 8 (N-120,119,120,123)	6720.1 (5861.07 to 7705.03)	9843.6 (8170.69 to 11858.92)	12638.3 (10883.83 to 14675.63)	790.8 (665.49 to 939.62)
Day 31 (N-121,121,124,122)	5327.6 (4640.84 to 6116.06)	7323.3 (6236 to 8600.25)	7943.4 (6942.16 to 9089.07)	762.9 (638.74 to 911.18)
Day 61 (N-121,121,124,120)	5268.4 (4639.84 to 5982.16)	6783.1 (5782.42 to 7956.92)	7575.8 (6633.19 to 8652.41)	875.6 (734.11 to 1044.4)

Day 91 (N-116,119,123,118)	4110.7 (3564.87 to 4740.12)	5186.7 (4357.63 to 6173.57)	5067.9 (4451.73 to 5769.4)	840.0 (717.87 to 982.93)

Statistical analyses

No statistical analyses for this end point

Secondary: Anti-RSVPreF3 Immunoglobulin G (IgG) antibody concentrations

End point title	Anti-RSVPreF3 Immunoglobulin G (IgG) antibody concentrations

End point description:

Concentrations are presented as geometric mean concentrations (GMCs), expressed in Enzyme Linked Immunosorbent Assay (ELISA) units per millilitre (EL.U/mL), calculated on subjects with anti-RSVPreF3 antibody concentration equal to or above the assay cut-off 25 EL.U/mL.
The analysis was performed on the Per-protocol set which included all vaccinated subjects, meeting all protocol requirements and for whom immunogenicity results were available for the specified assay at the corresponding time-point.

End point type	Secondary

End point timeframe:

At pre-vaccination at screening (PRE), 7 days post vaccination (Day 8), 30 days post vaccination (Day 31), 60 days post vaccination (Day 61) and 90 days post vaccination (Day 91)

End point values	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group	Control Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	123	125	126	126
Units: EL.U/mL				
geometric mean (confidence interval 95%)				
PRE (N-123,125,126,126)	6753 (6032.53 to 7560.61)	6447 (5822.74 to 7138.39)	6738 (5954.89 to 7625.01)	5583 (5014.96 to 6215.1)
Day 8 (N-120,119,120,123)	83187 (75159.55 to 92072.87)	111915 (97936.91 to 127887.72)	145984 (131579.66 to 161966.03)	5902 (5270.51 to 6609.37)
Day 31 (N-121,121,124,123)	66153 (58990.44 to 74184.52)	85096 (75185.08 to 96313.02)	94360 (86517.06 to 102912.86)	5856 (5165.49 to 6639.47)
Day 61 (N-121,121,124,120)	55170 (49687.49 to 61258)	65007 (57805.13 to 73106.25)	71401 (66038.58 to 77198.53)	6100 (5355.93 to 6948.09)
Day 91 (N-116,119,123,118)	39602 (34650.65 to 45261.85)	47629 (41925.98 to 54108.51)	51424 (46747.32 to 56569.61)	6692 (5722.81 to 7825)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Solicited adverse events were collected during the 7-day follow-up period and unsolicited adverse events during the 30-day follow-up period. Serious adverse events were collected from Day 1 up to Day 181.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	RSV MAT formulation 1 Group
Reporting group description:	
Subjects receive a single dose (30 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	RSV MAT formulation 2 Group
Reporting group description:	
Subjects receive a single dose (60 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	RSV MAT formulation 3 Group
Reporting group description:	
Subjects receive a single dose (120 µg) injection of the investigational RSV maternal vaccine (GSK3888550A) at Day 1, intramuscularly into the deltoid region of the non-dominant arm	
Reporting group title	Control Group
Reporting group description:	
Subjects receive a single placebo saline injection at Day 1, intramuscularly into the deltoid region of the non-dominant arm	

Serious adverse events	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Umbilical hernia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (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

Diverticulitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (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

Serious adverse events	Control Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 126 (1.59%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Gastrointestinal disorders			
Umbilical hernia			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticulitis			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	RSV MAT formulation 1 Group	RSV MAT formulation 2 Group	RSV MAT formulation 3 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	94 / 124 (75.81%)	96 / 126 (76.19%)	105 / 126 (83.33%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Hypertension			

subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Peripheral coldness			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	59 / 124 (47.58%)	64 / 126 (50.79%)	67 / 126 (53.17%)
occurrences (all)	59	64	67
Fatigue			
subjects affected / exposed	42 / 124 (33.87%)	49 / 126 (38.89%)	41 / 126 (32.54%)
occurrences (all)	43	49	41
Injection site inflammation			
subjects affected / exposed	8 / 124 (6.45%)	14 / 126 (11.11%)	10 / 126 (7.94%)
occurrences (all)	8	14	10
Injection site swelling			
subjects affected / exposed	5 / 124 (4.03%)	7 / 126 (5.56%)	6 / 126 (4.76%)
occurrences (all)	5	7	6
Pyrexia			
subjects affected / exposed	2 / 124 (1.61%)	0 / 126 (0.00%)	4 / 126 (3.17%)
occurrences (all)	2	0	4
Injection site bruising			
subjects affected / exposed	2 / 124 (1.61%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	2	1	1
Chills			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Peripheral swelling			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Axillary pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	2 / 126 (1.59%)
occurrences (all)	0	0	2
Influenza like illness			

subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Feeling cold			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Injection site induration			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Injury associated with device			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Swelling			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Vaccination site bruising			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Vaccination site haematoma			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 124 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Food allergy			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			

Dysmenorrhoea			
subjects affected / exposed	1 / 124 (0.81%)	2 / 126 (1.59%)	2 / 126 (1.59%)
occurrences (all)	2	2	2
Breast swelling			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Genital pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Menstrual disorder			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	4 / 124 (3.23%)	1 / 126 (0.79%)	4 / 126 (3.17%)
occurrences (all)	4	1	4
Cough			
subjects affected / exposed	1 / 124 (0.81%)	3 / 126 (2.38%)	3 / 126 (2.38%)
occurrences (all)	1	3	3
Rhinorrhoea			
subjects affected / exposed	1 / 124 (0.81%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	1	1	0
Nasal congestion			
subjects affected / exposed	1 / 124 (0.81%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	1	1	0
Paranasal sinus discomfort			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Asthma			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Sneezing			

subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Transaminases increased			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Dental restoration failure			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Hand fracture			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Ligament rupture			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Skin abrasion			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	43 / 124 (34.68%)	53 / 126 (42.06%)	63 / 126 (50.00%)
occurrences (all)	50	57	70

Dizziness			
subjects affected / exposed	1 / 124 (0.81%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	1	1	1
Paraesthesia			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	2 / 126 (1.59%)
occurrences (all)	1	0	2
Nerve compression			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Dysaesthesia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Neuralgia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Poor quality sleep			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Sciatica			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Thermohyperaesthesia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 124 (0.81%)	2 / 126 (1.59%)	3 / 126 (2.38%)
occurrences (all)	1	2	3
Lymphadenitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
External ear pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Hyperacusis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	30 / 124 (24.19%)	29 / 126 (23.02%)	23 / 126 (18.25%)
occurrences (all)	30	29	23
Diarrhoea			
subjects affected / exposed	2 / 124 (1.61%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	2	1	0
Nausea			
subjects affected / exposed	1 / 124 (0.81%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	2	1	0
Abdominal pain			
subjects affected / exposed	0 / 124 (0.00%)	2 / 126 (1.59%)	1 / 126 (0.79%)
occurrences (all)	0	2	1
Constipation			
subjects affected / exposed	2 / 124 (1.61%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	2	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	2
Food poisoning			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal pain			

subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Vomiting			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Urticaria			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Acne			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Night sweats			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Perioral dermatitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	4 / 124 (3.23%)	3 / 126 (2.38%)	0 / 126 (0.00%)
occurrences (all)	4	3	0
Pain in extremity			

subjects affected / exposed	4 / 124 (3.23%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	4	1	1
Arthralgia			
subjects affected / exposed	2 / 124 (1.61%)	2 / 126 (1.59%)	3 / 126 (2.38%)
occurrences (all)	2	2	3
Myalgia			
subjects affected / exposed	1 / 124 (0.81%)	2 / 126 (1.59%)	1 / 126 (0.79%)
occurrences (all)	1	2	1
Muscle spasms			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 124 (0.00%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	0	2	0
Neck pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	2 / 126 (1.59%)
occurrences (all)	0	0	3
Muscular weakness			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Muscle tightness			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Spinal pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	7 / 124 (5.65%)	7 / 126 (5.56%)	10 / 126 (7.94%)
occurrences (all)	8	7	11
Upper respiratory tract infection			
subjects affected / exposed	2 / 124 (1.61%)	4 / 126 (3.17%)	4 / 126 (3.17%)
occurrences (all)	2	4	4
Sinusitis			
subjects affected / exposed	2 / 124 (1.61%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	2	1	1
Urinary tract infection			
subjects affected / exposed	2 / 124 (1.61%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	2	1	0
Gastroenteritis			
subjects affected / exposed	1 / 124 (0.81%)	2 / 126 (1.59%)	0 / 126 (0.00%)
occurrences (all)	1	3	0
Gastroenteritis viral			
subjects affected / exposed	0 / 124 (0.00%)	2 / 126 (1.59%)	1 / 126 (0.79%)
occurrences (all)	0	2	1
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 124 (0.81%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	1	1	0
Influenza			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	1 / 126 (0.79%)
occurrences (all)	0	1	1
Bronchitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	1	0	1
Rhinitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Laryngitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0

Respiratory tract infection			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	1	0	0
Bacterial vaginosis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis bacterial			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Infectious mononucleosis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Nasal herpes			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	0 / 124 (0.00%)	1 / 126 (0.79%)	0 / 126 (0.00%)
occurrences (all)	0	1	0
Pharyngitis streptococcal			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	0 / 126 (0.00%)
occurrences (all)	0	0	0
Viral pharyngitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	0	0	1

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 124 (0.81%)	0 / 126 (0.00%)	1 / 126 (0.79%)
occurrences (all)	1	0	1

Non-serious adverse events	Control Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	83 / 126 (65.87%)		
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Peripheral coldness			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Injection site pain			
subjects affected / exposed	20 / 126 (15.87%)		
occurrences (all)	20		
Fatigue			
subjects affected / exposed	38 / 126 (30.16%)		
occurrences (all)	38		
Injection site inflammation			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Injection site swelling			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Injection site bruising			
subjects affected / exposed	2 / 126 (1.59%)		
occurrences (all)	2		

Chills				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Peripheral swelling				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Axillary pain				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Influenza like illness				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Feeling cold				
subjects affected / exposed	1 / 126 (0.79%)			
occurrences (all)	1			
Feeling hot				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Injection site induration				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Injury associated with device				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Pain				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Swelling				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Vaccination site bruising				
subjects affected / exposed	1 / 126 (0.79%)			
occurrences (all)	1			
Vaccination site haematoma				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			

Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Food allergy			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Breast swelling			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Genital pain			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Menstrual disorder			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Cough			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	2 / 126 (1.59%)		
occurrences (all)	2		
Nasal congestion			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Paranasal sinus discomfort			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		

Asthma subjects affected / exposed occurrences (all) Dyspnoea subjects affected / exposed occurrences (all) Sneezing subjects affected / exposed occurrences (all)	1 / 126 (0.79%) 1 0 / 126 (0.00%) 0 0 / 126 (0.00%) 0		
Investigations Alanine aminotransferase increased subjects affected / exposed occurrences (all) Aspartate aminotransferase increased subjects affected / exposed occurrences (all) Haemoglobin decreased subjects affected / exposed occurrences (all) Transaminases increased subjects affected / exposed occurrences (all)	 1 / 126 (0.79%) 1 1 / 126 (0.79%) 1 0 / 126 (0.00%) 0 1 / 126 (0.79%) 1		
Injury, poisoning and procedural complications Dental restoration failure subjects affected / exposed occurrences (all) Hand fracture subjects affected / exposed occurrences (all) Ligament rupture subjects affected / exposed occurrences (all) Skin abrasion subjects affected / exposed occurrences (all)	 0 / 126 (0.00%) 0 0 / 126 (0.00%) 0 0 / 126 (0.00%) 0 0 / 126 (0.00%) 0		
Cardiac disorders			

Tachycardia			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Headache			
subjects affected / exposed	38 / 126 (30.16%)		
occurrences (all)	50		
Dizziness			
subjects affected / exposed	2 / 126 (1.59%)		
occurrences (all)	2		
Paraesthesia			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Nerve compression			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Dysaesthesia			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Neuralgia			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Poor quality sleep			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Sciatica			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Thermohyperaesthesia			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Lymphadenopathy			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Lymphadenitis			

subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Neutropenia			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
External ear pain			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Hyperacusis			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Vertigo			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	27 / 126 (21.43%)		
occurrences (all)	27		
Diarrhoea			
subjects affected / exposed	2 / 126 (1.59%)		
occurrences (all)	2		
Nausea			
subjects affected / exposed	2 / 126 (1.59%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			

subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Food poisoning			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Gastrointestinal pain			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Hyperhidrosis			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Acne			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Perioral dermatitis			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Skin exfoliation			

subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	2 / 126 (1.59%)		
occurrences (all)	2		
Arthralgia			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Muscle spasms			
subjects affected / exposed	2 / 126 (1.59%)		
occurrences (all)	2		
Musculoskeletal pain			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Joint swelling			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Muscle tightness			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Musculoskeletal discomfort			

subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Pain in jaw			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Spinal pain			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 126 (3.17%)		
occurrences (all)	4		
Upper respiratory tract infection			
subjects affected / exposed	3 / 126 (2.38%)		
occurrences (all)	3		
Sinusitis			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Gastroenteritis viral			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Influenza			
subjects affected / exposed	1 / 126 (0.79%)		
occurrences (all)	1		
Bronchitis			
subjects affected / exposed	0 / 126 (0.00%)		
occurrences (all)	0		

Rhinitis				
subjects affected / exposed	1 / 126 (0.79%)			
occurrences (all)	1			
Laryngitis				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Oral herpes				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Respiratory tract infection				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Viral infection				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Bacterial vaginosis				
subjects affected / exposed	1 / 126 (0.79%)			
occurrences (all)	1			
Conjunctivitis bacterial				
subjects affected / exposed	1 / 126 (0.79%)			
occurrences (all)	1			
Cystitis				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Gastroenteritis norovirus				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Infection				
subjects affected / exposed	1 / 126 (0.79%)			
occurrences (all)	1			
Infectious mononucleosis				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			
Nasal herpes				
subjects affected / exposed	0 / 126 (0.00%)			
occurrences (all)	0			

Pharyngitis subjects affected / exposed occurrences (all) Pharyngitis streptococcal subjects affected / exposed occurrences (all) Viral pharyngitis subjects affected / exposed occurrences (all)	0 / 126 (0.00%) 0 1 / 126 (0.79%) 1 0 / 126 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	0 / 126 (0.00%) 0		

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