Clinical trial results:
A Phase III, randomized, open-label, active vaccine-controlled crossover study to evaluate the reactogenicity, safety and immune response of unadjuvanted RSV maternal vaccine in healthy non-pregnant girls from 9 to 17 years of age, and in non-pregnant adult women from 18 to 49 years of age

Summary

EudraCT number	2021-004003-41
Trial protocol	ES
Global end of trial date	03 August 2022

Results information

Result version number	v1 (current)
This version publication date	22 February 2023
First version publication date	22 February 2023
Summary attachment (see zip file)	Statement on cancellation before enrollment and results availability - 217354 (Statement on cancellation before enrollment and results availability - 217354.pdf)

Trial information

Trial identification

Sponsor protocol code	217354

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT05169905
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, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-002821-PIP01-20
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	21 October 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 August 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

• To evaluate the safety following administration of RSV maternal vaccine in the pediatric (9-17 YOA) and adult (18-49 YOA) study groups during the entire study period (180 days post RSV maternal vaccination).
• To evaluate the reactogenicity and safety following administration of RSV maternal vaccine and dTpa control vaccine in the pediatric and adult study groups up to 30 days (including day of study intervention administration).

Protection of trial subjects:

Study participants were observed closely for at least 30 minutes after the administration of the study intervention(s). Appropriate medical treatment was readily available during the observation period in case of anaphylaxis, syncope. Vaccines/products were administered by qualified and trained personnel. Vaccines/products were administered only to eligible participants that had no contraindications to any components of the vaccines/products. Study participants were followed-up for 180 days after the administration of study intervention(s).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	02 February 2022
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	United States: 9
Worldwide total number of subjects	9
EEA total number of subjects	0

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	0

months)	
Children (2-11 years)	2
Adolescents (12-17 years)	0
Adults (18-64 years)	7
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was planned to enroll 252 participants in 4 groups as per Protocol. However, due to early stoppage of enrolment and further vaccination, only 9 participants were enrolled in the study, out of which 8 participants were assigned to individual groups, except for the dTpa_RSV-P group, hence this group was not included in the results record.

Pre-assignment

Screening details:

Out of the 9 participants enrolled in the study, 1 participant withdrew consent before being assigned to any of the groups and was not vaccinated. 8 participants were vaccinated and were included in the Exposed set.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	RSV_dTpa-P Group

Arm description:

Healthy non-pregnant girls 9-17 years of age received a single dose of RSV MAT vaccine at Day 1 and were scheduled to receive a single dose of dTpa vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). Participants who were enrolled and were due to receive the dTpa vaccine at Day 31, did no longer receive the dTpa as part of this study, but they were provided with an option to decide to receive dTpa vaccination as part of standard of care/local recommendation on immunization.

Arm type	Experimental
Investigational medicinal product name	RSV MAT
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 dose of the RSV MAT vaccine reconstituted with NaCl solution was administered in the non-dominant arm at Day 1.

Arm title	RSV_dTpa-A Group

Arm description:

Healthy non-pregnant adult women 18-49 years of age received a single dose of RSV MAT vaccine at Day 1 and were scheduled to receive a single dose of dTpa vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). Participants who were enrolled and were due to receive the dTpa vaccine at Day 31, did no longer receive the dTpa as part of this study, but they were provided with an option to decide to receive dTpa vaccination as part of standard of care/local recommendation on immunization.

Arm type	Experimental
Investigational medicinal product name	RSV MAT
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 dose of the RSV MAT vaccine reconstituted with NaCl solution was administered in the non-

dominant arm at Day 1.

Arm title	dTpa_RSV-A Group

Arm description:

Healthy non-pregnant adult women 18-49 years of age received a single dose of dTpa vaccine at Day 1 and were scheduled to receive a single dose of RSV MAT vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). RSV MAT vaccine was no longer administered to participants at Day 31.

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

Dosage and administration details:

Single dose of the dTpa vaccine was administered in the non-dominant arm at Day 1.

Number of subjects in period 1[1]	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group
Started	1	3	4
Completed	1	3	4

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Out of the 9 participants enrolled in the study, 1 participant withdrew consent before being assigned to any of the groups and was not vaccinated. 8 participants were vaccinated and were included in the Exposed set.

Baseline characteristics

Reporting groups	
Reporting group title	RSV_dTpa-P Group
Reporting group description:	
Healthy non-pregnant girls 9-17 years of age received a single dose of RSV MAT vaccine at Day 1 and were scheduled to receive a single dose of dTpa vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). Participants who were enrolled and were due to receive the dTpa vaccine at Day 31, did no longer receive the dTpa as part of this study, but they were provided with an option to decide to receive dTpa vaccination as part of standard of care/local recommendation on immunization.	
Reporting group title	RSV_dTpa-A Group
Reporting group description:	
Healthy non-pregnant adult women 18-49 years of age received a single dose of RSV MAT vaccine at Day 1 and were scheduled to receive a single dose of dTpa vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). Participants who were enrolled and were due to receive the dTpa vaccine at Day 31, did no longer receive the dTpa as part of this study, but they were provided with an option to decide to receive dTpa vaccination as part of standard of care/local recommendation on immunization.	
Reporting group title	dTpa_RSV-A Group
Reporting group description:	
Healthy non-pregnant adult women 18-49 years of age received a single dose of dTpa vaccine at Day 1 and were scheduled to receive a single dose of RSV MAT vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). RSV MAT vaccine was no longer administered to participants at Day 31.	

Reporting group values	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group
Number of subjects	1	3	4
Age categorical Units: Participants			
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)	1	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	3	4
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Age and its descriptive analysis is presented for adult participants only. There was only one participant in the pediatric age group, hence the mean and standard deviation could not be calculated, and therefore the age continuous data for this group is indicated as 0.			
Units: years			
arithmetic mean	0	42.3	38.0
standard deviation	± 0	± 2.5	± 9.4
Sex: Female, Male Units: Participants			
Female	1	3	4
Male	0	0	0

Race/Ethnicity, Customized Units: Subjects			
BLACK OR AFRICAN AMERICAN	1	0	0
WHITE	0	3	4

Reporting group values	Total		
Number of subjects	8		
Age categorical Units: Participants			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	1		
Adolescents (12-17 years)	0		
Adults (18-64 years)	7		
From 65-84 years	0		
85 years and over	0		
Age Continuous			
Age and its descriptive analysis is presented for adult participants only. There was only one participant in the pediatric age group, hence the mean and standard deviation could not be calculated, and therefore the age continuous data for this group is indicated as 0.			
Units: years arithmetic mean standard deviation	- -		
Sex: Female, Male Units: Participants			
Female	8		
Male	0		
Race/Ethnicity, Customized Units: Subjects			
BLACK OR AFRICAN AMERICAN	1		
WHITE	7		

End points

End points reporting groups

Reporting group title	RSV_dTpa-P Group

Reporting group description:

Healthy non-pregnant girls 9-17 years of age received a single dose of RSV MAT vaccine at Day 1 and were scheduled to receive a single dose of dTpa vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). Participants who were enrolled and were due to receive the dTpa vaccine at Day 31, did no longer receive the dTpa as part of this study, but they were provided with an option to decide to receive dTpa vaccination as part of standard of care/local recommendation on immunization.

Reporting group title	RSV_dTpa-A Group

Reporting group description:

Healthy non-pregnant adult women 18-49 years of age received a single dose of RSV MAT vaccine at Day 1 and were scheduled to receive a single dose of dTpa vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). Participants who were enrolled and were due to receive the dTpa vaccine at Day 31, did no longer receive the dTpa as part of this study, but they were provided with an option to decide to receive dTpa vaccination as part of standard of care/local recommendation on immunization.

Reporting group title	dTpa_RSV-A Group

Reporting group description:

Healthy non-pregnant adult women 18-49 years of age received a single dose of dTpa vaccine at Day 1 and were scheduled to receive a single dose of RSV MAT vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). RSV MAT vaccine was no longer administered to participants at Day 31.

Primary: Number of participants reporting any serious adverse events (SAEs)

End point title	Number of participants reporting any serious adverse events (SAEs)[1]

End point description:

An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant or results in abnormal pregnancy outcomes. Any is defined as the occurrence of the symptom regardless of intensity grade or relationship to vaccination.
The analysis was performed on the Exposed Set, which included all participants who received the study intervention (RSV maternal vaccine or dTpa vaccine).

End point type	Primary

End point timeframe:

During the entire study period (from Day 1 up to Day 181)

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	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	4	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants reporting adverse events (AEs)/SAEs leading to study withdrawal

End point title	Number of participants reporting adverse events (AEs)/SAEs leading to study withdrawal[2]

End point description:

An AE is any untoward medical occurrence, symptom, or disease in a clinical study participant that is temporally associated with the study intervention. The AE may or may not be considered related to the study intervention.
An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant or results in abnormal pregnancy outcomes.
A participant is considered to have withdrawn from the study if no new study procedure has been performed or no new information has been collected for him/her since the date of withdrawal/last contact.
The analysis was performed on the Exposed Set.

End point type	Primary

End point timeframe:

During the entire study period (from Day 1 up to Day 181)

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	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	4	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants reporting any solicited administration site events

End point title	Number of participants reporting any solicited administration site events[3]

End point description:

Assessed solicited administration site events include pain, erythema and swelling. Any pain = occurrence of the symptom regardless of intensity grade. Any erythema and swelling = symptom reported with a surface diameter lower than or equal to 20 millimeters.
The analysis was performed on the Solicited Safety Set, which included all participants in the Exposed Set who have solicited safety data.

End point type	Primary

End point timeframe:

During the 7 days follow-up period post-Dose 1

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	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	4	
Units: Participants				
Pain	1	1	3	
Erythema	0	0	1	
Swelling	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants reporting any solicited systemic events

End point title	Number of participants reporting any solicited systemic

End point description:

Assessed solicited systemic events include fatigue, headache, gastrointestinal (GI) symptoms (nausea, vomiting, diarrhea, abdominal pain) and fever. The preferred location for measuring temperature is the oral cavity. Fever is defined as temperature equal to or above (≥) 38.0 °C/100.4°F. Any is defined as the occurrence of the symptom regardless of intensity grade.
The analysis was performed on the Solicited Safety Set.

End point type	Primary

End point timeframe:

During the 7 days follow-up period post-Dose 1

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	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	4	
Units: Participants				
Fatigue	0	1	1	
Headache	0	1	2	
Nausea	0	1	0	
Vomiting	0	0	0	
Diarrhea	0	2	2	
Abdominal pain	0	1	0	
Fever	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants reporting any unsolicited AEs

End point title	Number of participants reporting any unsolicited AEs[5]

End point description:

An unsolicited AE is an event reported in addition to those solicited during the clinical study. Also, any 'solicited' symptom with onset outside the specified period of follow-up for solicited symptoms is reported as an unsolicited adverse event. Any is defined as the occurrence of the unsolicited AE regardless of intensity grade or relationship to vaccination.
The analysis was performed on the Exposed Set.

End point type	Primary

End point timeframe:

During the 30 days follow-up period post-Dose 1

Notes:

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

End point values	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	4	
Units: Participants	0	1	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants reporting SAEs and medically attended adverse events (MAEs)

End point title	Number of participants reporting SAEs and medically attended adverse events (MAEs)[6]

End point description:

An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant or results in abnormal pregnancy outcomes. An MAE is an unsolicited AE for which the participants receive medical attention, defined as symptoms or illnesses requiring a hospitalization, or an emergency room visit, or visit to/by a health care provider.
The analysis was performed on the Exposed Set.

End point type	Primary

End point timeframe:

During the 30 days follow-up period post-Dose 1

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	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	4	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants reporting AEs/SAEs/MAEs leading to study withdrawal

End point title	Number of participants reporting AEs/SAEs/MAEs leading to study withdrawal[7]

End point description:

An AE is any untoward medical occurrence, symptom, or disease in a clinical study participant that is temporally associated with the study intervention. The AE may or may not be considered related to the study intervention.
An SAE is any untoward medical occurrence that results in death, is life-threatening, requires hospitalization or prolongation of existing hospitalization, results in disability/incapacity, is a congenital anomaly/birth defect in the offspring of a study participant or results in abnormal pregnancy outcomes.
An MAE is an unsolicited AE for which the participants received medical attention defined as symptoms or illnesses requiring a hospitalization, or an emergency room visit, or visit to/by a health care provider.
A participant is considered to have withdrawn from the study if no new study procedure has been performed or no new information has been collected for him/her since the date of withdrawal/last contact.
The analysis was performed on the Exposed Set.

End point type	Primary

End point timeframe:

During the 30 days follow-up period post-Dose 1

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	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	3	4	
Units: Participants	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 1

End point title	RSV-A neutralizing antibody titers for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 1[8]

End point description:

RSV-A neutralizing antibody titer expressed in Estimated Dose: serum dilution giving a 60% reduction of the signal compared to a control without serum (ED60) is presented for each participant who received the RSV MAT vaccine and was assigned to the respective group.
Due to a small number of participants assigned to the study groups, geometric mean titers could not be summarized for this outcome measure. Hence, antibody titer was reported for each participant evaluated in the respective arm, who received the RSV MAT vaccine and had individual immunogenicity data available at the specified time point.

End point type	Secondary

End point timeframe:

At pre-dosing (Day 1)

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for participants who received the RSV MAT vaccine.

End point values	RSV_dTpa-P Group	RSV_dTpa-A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Titers (ED60)				
number (not applicable)				
Participant 1 (N=1;1)	86	1355		
Participant 2 (N=0;1)	0	792		
Participant 3 (N=0;1)	0	177		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-A neutralizing antibody titers for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 31

End point title	RSV-A neutralizing antibody titers for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 31[9]

End point description:

RSV-A neutralizing antibody titer expressed in ED60 is presented for each participant who received the RSV MAT vaccine and was assigned to the respective group.
Due to a small number of participants assigned to the study groups, geometric mean titers could not be summarized for this outcome measure. Hence, antibody titer was reported for each participant evaluated in the respective arm, who received the RSV MAT vaccine and had individual immunogenicity data available at the specified time point.

End point type	Secondary

End point timeframe:

At 30 days post-RSV MAT vaccine administration (Day 31)

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for participants who received the RSV MAT vaccine.

End point values	RSV_dTpa-P Group	RSV_dTpa-A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Titers (ED60)				
number (not applicable)				
Participant 1 (N=1;1)	1702	21707		
Participant 2 (N=0;1)	0	38258		
Participant 3 (N=0;1)	0	17765		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing antibody titers for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 1

End point title	RSV-B neutralizing antibody titers for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 1[10]

End point description:

RSV-B neutralizing antibody titer expressed in ED60 is presented for each participant who received the RSV MAT vaccine and was assigned to the respective group.
Due to a small number of participants assigned to the study groups, geometric mean titers could not be summarized for this outcome measure. Hence, antibody titer was reported for each participant evaluated in the respective arm, who received the RSV MAT vaccine and had individual immunogenicity data available at the specified time point.

End point type	Secondary

End point timeframe:

At pre-dosing (Day 1)

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for participants who received the RSV MAT vaccine.

End point values	RSV_dTpa-P Group	RSV_dTpa-A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Titers (ED60)				
number (not applicable)				
Participant 1 (N=1;1)	373	2434		
Participant 2 (N=0;1)	0	525		
Participant 3 (N=0;1)	0	461		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV-B neutralizing antibody titers for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 31

End point title	RSV-B neutralizing antibody titers for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 31[11]

End point description:

RSV-B neutralizing antibody titer expressed in ED60 is presented for each participant who received the RSV MAT vaccine and was assigned to the respective group.
Due to a small number of participants assigned to the study groups, geometric mean titers could not be summarized for this outcome measure. Hence, antibody titer was reported for each participant evaluated in the respective arm, who received the RSV MAT vaccine and had individual immunogenicity data available at the specified time point.

End point type	Secondary

End point timeframe:

At 30 days post-RSV MAT vaccine administration (Day 31)

Notes:

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

Justification: This endpoint is only reporting values for participants who received the RSV MAT vaccine.

End point values	RSV_dTpa-P Group	RSV_dTpa-A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: Titers (ED60)				
number (not applicable)				
Participant 1 (N=1;1)	2089	138336		
Participant 2 (N=0;1)	0	14233		
Participant 3 (N=0;1)	0	34743		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT immunoglobulin G (IgG) antibody concentrations for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 1

End point title	RSV MAT immunoglobulin G (IgG) antibody concentrations for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 1[12]

End point description:

RSV MAT IgG antibody concentration expressed in ELISA units per milliliter (EU/mL) is presented for each participant who received the RSV MAT vaccine and was assigned to the respective group.
Due to a small number of participants assigned to the study groups, geometric mean concentrations could not be summarized for this outcome measure. Hence, antibody concentration was reported for each participant evaluated in the respective arm, who received the RSV MAT vaccine and had individual immunogenicity data available at the specified time point.

End point type	Secondary

End point timeframe:

At pre-dosing (Day 1)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for participants who received the RSV MAT vaccine.

End point values	RSV_dTpa-P Group	RSV_dTpa-A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: EU/mL				
number (not applicable)				
Participant 1 (N=1;1)	1949	4967		
Participant 2 (N=0;1)	0	3279		
Participant 3 (N=0;1)	0	4727		

Statistical analyses

No statistical analyses for this end point

Secondary: RSV MAT IgG antibody concentrations for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 31

End point title	RSV MAT IgG antibody concentrations for participants in RSV_dTpa-P Group and RSV_dTpa-A Group at Day 31[13]

End point description:

RSV MAT IgG antibody concentration expressed in EU/mL is presented for each participant who received the RSV MAT vaccine and was assigned to the respective group.
Due to a small number of participants assigned to the study groups, geometric mean concentrations could not be summarized for this outcome measure. Hence, antibody concentration was reported for each participant evaluated in the respective arm, who received the RSV MAT vaccine and had individual immunogenicity data available at the specified time point.

End point type	Secondary

End point timeframe:

At 30 days post-RSV MAT vaccine administration (Day 31)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint is only reporting values for participants who received the RSV MAT vaccine.

End point values	RSV_dTpa-P Group	RSV_dTpa-A Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	1	3		
Units: EU/mL				
number (not applicable)				
Participant 1 (N=1;1)	50193	149510		
Participant 2 (N=0;1)	0	218190		
Participant 3 (N=0;1)	0	402812		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited AEs were collected during the 7-day follow-up period after vaccination. Unsolicited AEs were collected during the 30-day follow-up period after vaccination. SAEs were collected from study start (Day 1) up to 180 days after vaccination (Day 181).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

Reporting groups

Reporting group title	RSV_dTpa-P Group

Reporting group description:

Healthy non-pregnant girls 9-17 years of age received a single dose of RSV MAT vaccine at Day 1 and were scheduled to receive a single dose of dTpa vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). Participants who were enrolled and were due to receive the dTpa vaccine at Day 31, did no longer receive the dTpa as part of this study, but they were provided with an option to decide to receive dTpa vaccination as part of standard of care/local recommendation on immunization.

Reporting group title	RSV_dTpa-A Group

Reporting group description:

Healthy non-pregnant adult women 18-49 years of age received a single dose of RSV MAT vaccine at Day 1 and were scheduled to receive a single dose of dTpa vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). Participants who were enrolled and were due to receive the dTpa vaccine at Day 31, did no longer receive the dTpa as part of this study, but they were provided with an option to decide to receive dTpa vaccination as part of standard of care/local recommendation on immunization.

Reporting group title	dTpa_RSV-A Group

Reporting group description:

Healthy non-pregnant adult women 18-49 years of age received a single dose of dTpa vaccine at Day 1 and were scheduled to receive a single dose of RSV MAT vaccine at Day 31 and to be followed-up until end of study (180 days post-vaccine administration). RSV MAT vaccine was no longer administered to participants at Day 31.

Serious adverse events	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

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

Non-serious adverse events	RSV_dTpa-P Group	RSV_dTpa-A Group	dTpa_RSV-A Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 1 (100.00%)	2 / 3 (66.67%)	3 / 4 (75.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	0	3	2
General disorders and administration site conditions			
Administration site pain			
subjects affected / exposed	1 / 1 (100.00%)	1 / 3 (33.33%)	3 / 4 (75.00%)
occurrences (all)	1	1	9
Fatigue			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	5	2
Administration site erythema			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 1 (0.00%)	2 / 3 (66.67%)	2 / 4 (50.00%)
occurrences (all)	0	2	2
Abdominal pain			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Nausea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Hypomenorrhoea			
subjects affected / exposed	0 / 1 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 1 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 March 2022	• Following a recommendation from the Independent Data Monitoring Committee of NCT04605159 (RSV MAT 009), GSK made the decision to stop enrolment and vaccination in the study. Ongoing study participants continued to be monitored as part of the study. • There were no new participants included in this study. There were 9 participants enrolled in this study. However, one subject withdrew after giving consent but before randomization and any study intervention administration. Thus, safety follow-up continued until the end of the study period (180 days post vaccination) for all 8 participants enrolled and vaccinated at a study site in the US. • The vaccination planned at Visit 2 was removed. Therefore, Contact 2 at Day 38 and Visit 3 at Day 61 were not applicable anymore. Visit 4a (Day 181) and Visit 4b (Day 211) were replaced by a telephone contact at Day 181. • A blood sample for immunogenicity assessment in the study participants who received first dose of RSV Maternal vaccine continued to be collected at Visit 2 only. No other blood samples were collected. • All planned objectives were analysed and reported in a descriptive manner for the 8 enrolled and vaccinated participants.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported