



Clinical trial results:

A phase III, randomised, observer-blind, multicentre study to evaluate the immunogenicity and safety of a 2-dose vaccination with the new process manufactured adjuvanted pandemic H1N1 influenza candidate vaccine in children aged 3 to 9 years old.

Summary

EudraCT number	2009-015960-32
Trial protocol	CZ
Global end of trial date	14 January 2011

Results information

Result version number	v2 (current)
This version publication date	15 December 2022
First version publication date	23 May 2015
Version creation reason	• Correction of full data set Correction of full data set and alignment between registries.

Trial information

Trial identification

Sponsor protocol code	113810
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01014091
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline Biologicals
Sponsor organisation address	Rue de l'Institut 89, Rixensart, Belgium, B-1330
Public contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Trials Call Center, GlaxoSmithKline Biologicals, 044 2089-904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 May 2011
Is this the analysis of the primary completion data?	Yes
Primary completion date	14 January 2011
Global end of trial reached?	Yes
Global end of trial date	14 January 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate whether the humoral immune response of the 3.75 µg dosage with AS03A H1N1 candidate vaccine meets or exceeds the CHMP criteria at 21 days post-dose 2 vaccination.

To evaluate whether the humoral immune response of the 1.9 µg dosage with AS03B H1N1 candidate vaccine meets or exceeds the CHMP criteria at 21 days post-dose 2 vaccination.

Protection of trial subjects:

The vaccines were observed closely for at least 60 minutes following the administration of the vaccine with appropriate medical treatment readily available in case of a rare anaphylactic reaction.

Vaccines were administered by qualified and trained personnel. Vaccines were administered only to eligible subjects that had no contraindications to any components of the vaccines.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 December 2009
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	Czech Republic: 60
Worldwide total number of subjects	60
EEA total number of subjects	60

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)	60
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

From a total of 60 subjects enrolled in the study only 58 were vaccinated.

Pre-assignment period milestones

Number of subjects started	60
Number of subjects completed	58

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Unvaccinated: 2
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Period 1

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

Blinding implementation details:

Data was collected in an observer-blind manner. By observer-blind, it was meant that during the course of the study, the vaccine recipient and those responsible for the evaluation of any study endpoint (e.g. safety, reactogenicity) were all unaware of which vaccine was administered. To do so, vaccine preparation and administration was done by authorized medical personnel who did not participate in any of the study clinical evaluation assay.

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK2340272A F1 Y3-5 Group

Arm description:

Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 1 (F1) in the deltoid region of the arm, according to a 0-21 day schedule.

Arm type	Experimental
Investigational medicinal product name	GSK2340272A vaccine
Investigational medicinal product code	
Other name	GSK pandemic vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

The vaccine was administered intramuscularly in the deltoid of the arm.

Arm title	GSK2340272A F1 Y6-9 Group
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Arm description:

Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 1 (F1) in the deltoid region of the arm, according to a 0-21 day schedule.

Arm type	Experimental
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Investigational medicinal product name	GSK2340272A vaccine
Investigational medicinal product code	
Other name	GSK pandemic vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

The vaccine was administered intramuscularly in the deltoid of the arm.

Arm title	GSK2340272A F2 Y3-5 Group
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Arm description:

Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 2 (F2) in the deltoid region of the arm, according to a 0-21 day schedule.

Arm type	Experimental
Investigational medicinal product name	GSK2340272A vaccine
Investigational medicinal product code	
Other name	GSK pandemic vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

The vaccine was administered intramuscularly in the deltoid of the arm.

Arm title	GSK2340272A F2 Y6-9 Group
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Arm description:

Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 2 (F2) in the deltoid region of the arm, according to a 0-21 day schedule.

Arm type	Experimental
Investigational medicinal product name	GSK2340272A vaccine
Investigational medicinal product code	
Other name	GSK pandemic vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

The vaccine was administered intramuscularly in the deltoid of the arm.

Arm title	GSK2340272A F3 Y3-5 Group
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Arm description:

Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 3 (F3) in the deltoid region of the arm, according to a 0-21 day schedule.

Arm type	Experimental
Investigational medicinal product name	GSK2340272A vaccine
Investigational medicinal product code	
Other name	GSK pandemic vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

The vaccine was administered intramuscularly in the deltoid of the arm.

Arm title	GSK2340272A F3 Y6-9 Group
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Arm description:

Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 3 (F3) in the deltoid region of the arm, according to a 0-21 day schedule.

Arm type	Experimental
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Investigational medicinal product name	GSK2340272A vaccine
Investigational medicinal product code	
Other name	GSK pandemic vaccine
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

The vaccine was administered intramuscularly in the deltoid of the arm.

Number of subjects in period 1^[1]	GSK2340272A F1 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y3-5 Group
Started	7	13	5
Completed	7	13	5

Number of subjects in period 1^[1]	GSK2340272A F2 Y6-9 Group	GSK2340272A F3 Y3-5 Group	GSK2340272A F3 Y6-9 Group
Started	15	6	12
Completed	15	6	12

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: From a total of 60 subjects enrolled in this study, two subjects were excluded from the TVC because the study vaccine dose was not administered although a subject number was allocated.

Baseline characteristics

Reporting groups

Reporting group title	GSK2340272A F1 Y3-5 Group
Reporting group description: Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 1 (F1) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F1 Y6-9 Group
Reporting group description: Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 1 (F1) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F2 Y3-5 Group
Reporting group description: Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 2 (F2) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F2 Y6-9 Group
Reporting group description: Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 2 (F2) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F3 Y3-5 Group
Reporting group description: Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 3 (F3) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F3 Y6-9 Group
Reporting group description: Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 3 (F3) in the deltoid region of the arm, according to a 0-21 day schedule.	

Reporting group values	GSK2340272A F1 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y3-5 Group
Number of subjects	7	13	5
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	4.1	7.5	3.8
standard deviation	± 0.9	± 1.2	± 0.84

Gender categorical Units: Subjects			
Female	3	7	2
Male	4	6	3

Reporting group values	GSK2340272A F2 Y6-9 Group	GSK2340272A F3 Y3-5 Group	GSK2340272A F3 Y6-9 Group
Number of subjects	15	6	12
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age continuous Units: years			
arithmetic mean	7.3	3.8	7.6
standard deviation	± 0.9	± 0.98	± 0.9
Gender categorical Units: Subjects			
Female	4	1	3
Male	11	5	9

Reporting group values	Total		
Number of subjects	58		
Age categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	0		
Newborns (0-27 days)	0		
Infants and toddlers (28 days-23 months)	0		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age continuous Units: years			
arithmetic mean	-		
standard deviation	-		
Gender categorical Units: Subjects			
Female	20		
Male	38		

End points

End points reporting groups

Reporting group title	GSK2340272A F1 Y3-5 Group
Reporting group description: Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 1 (F1) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F1 Y6-9 Group
Reporting group description: Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 1 (F1) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F2 Y3-5 Group
Reporting group description: Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 2 (F2) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F2 Y6-9 Group
Reporting group description: Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 2 (F2) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F3 Y3-5 Group
Reporting group description: Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 3 (F3) in the deltoid region of the arm, according to a 0-21 day schedule.	
Reporting group title	GSK2340272A F3 Y6-9 Group
Reporting group description: Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 3 (F3) in the deltoid region of the arm, according to a 0-21 day schedule.	
Subject analysis set title	GSK2340272A Formulation 1 Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects received 2 doses of Flu vaccine formulation 1 according to a 0, 21-day schedule. Enrolment was further stratified by age: 3 – 5 years and 6 – 9 years.	
Subject analysis set title	GSK2340272A Formulation 2 Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects received 2 doses of Flu vaccine formulation 2 according to a 0, 21-day schedule. Enrolment was further stratified by age: 3 – 5 years and 6 – 9 years.	
Subject analysis set title	GSK2340272A Formulation 3 Group
Subject analysis set type	Sub-group analysis
Subject analysis set description: Subjects received 2 doses of Flu vaccine formulation 3 according to a 0, 21-day schedule. Enrolment was further stratified by age: 3 – 5 years and 6 – 9 years.	

Primary: Haemagglutination inhibition (HI) antibody titers against vaccine H1N1 antigen

End point title	Haemagglutination inhibition (HI) antibody titers against vaccine H1N1 antigen ^[1]
End point description: Humoral immune response in terms of vaccine H1N1 haemagglutination inhibition (HI) antibodies against A/California/7/2009 (H1N1)v-like virus (Flu A/CAL/7/09) has been assessed. Antibody titers	

were presented as geometric mean titers (GMTs).

The analysis was performed on the According-to-Protocol (ATP) cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Primary
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End point timeframe:

At Day 42

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	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Titers				
geometric mean (confidence interval 95%)				
Flu A/CAL/7/09	954.6 (730 to 1248.4)	838.1 (647 to 1085.5)	359.1 (219.8 to 586.9)	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seropositive subjects for HI antibodies

End point title	Number of seropositive subjects for HI antibodies ^[2]
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End point description:

A seropositive subject was defined as a subject with a serum HI titer equal to or above ($\geq$) 1:10. The flu strain assessed was Flu A/CAL/7/09.

The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Primary
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End point timeframe:

At Day 42

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	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Subjects				
Flu A/CAL/7/09 (N=13; 9; 12)	13	9	12	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroconverted subjects in terms of HI antibodies

End point title	Number of seroconverted subjects in terms of HI antibodies ^[3]
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End point description:

Seroconversion (SCR) was defined as: For initially seronegative subjects [pre-vaccination titer below (<) 1:10], a post-vaccination titer $\geq$ 1:40. For initially seropositive subjects (pre-vaccination titer $\geq$ 1:10), at least a 4-fold increase in post-vaccination titer. The flu strain assessed was Flu A/CAL/7/09. The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Primary
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End point timeframe:

At Day 42

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	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Subjects				
Flu A/CAL/7/09	13	9	12	

Statistical analyses

No statistical analyses for this end point

Primary: Number of seroprotected subjects for HI antibodies

End point title	Number of seroprotected subjects for HI antibodies ^[4]
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End point description:

A seroprotected subject was defined as a vaccinated subject with a serum HI titer $\geq$ 1:40, which is usually accepted as indicating protection. The flu strain assessed was Flu A/CAL/7/09. The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Primary
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End point timeframe:

At Day 42

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	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Subjects				
Flu A/CAL/7/09	13	9	12	

Statistical analyses

No statistical analyses for this end point

Primary: Geometric mean fold increase (GMFR) for serum HI antibody titer

End point title	Geometric mean fold increase (GMFR) for serum HI antibody titer ^[5]
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End point description:

GMFR, also called seroconversion factor (SCF), was defined as the fold increase in serum HI geometric mean titers (GMTs) post-vaccination compared to pre-vaccination. The flu strain assessed was Flu A/CAL/7/09.

The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Primary
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End point timeframe:

At Day 42

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	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Fold increase				
geometric mean (confidence interval 95%)				
Flu A/CAL/7/09	64 (25.9 to 158.2)	71.9 (24.4 to 212.1)	40.3 (27 to 60.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: HI antibody titers against vaccine H1N1 antigen

End point title	HI antibody titers against vaccine H1N1 antigen
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End point description:

Humoral immune response in terms of vaccine H1N1 haemagglutination inhibition (HI) antibodies against A/California/7/2009 (H1N1)v-like virus (Flu A/CAL/7/09) has been assessed. Antibody titers were presented as geometric mean titers (GMTs).

The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Secondary
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End point timeframe:

At Day 0, Day 21 and Month 7

End point values	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Titers				
geometric mean (confidence interval 95%)				
Flu A/CAL/7/09, Day 0	14.9 (6.9 to 32)	11.7 (4.2 to 32.1)	8.9 (4.9 to 16.2)	
Flu A/CAL/7/09, Day 21	429.1 (268.9 to 684.6)	285.3 (137.7 to 591.1)	123.2 (40.5 to 374.9)	
Flu A/CAL/7/09, Month 7	155.9 (104.1 to 233.6)	108.7 (61.2 to 192.9)	84.8 (53.7 to 134.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seropositive subjects for HI antibodies

End point title	Number of seropositive subjects for HI antibodies
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End point description:

A seropositive subject was defined as a subject with a serum HI titer equal to or above ($\geq$) 1:10. The flu strain assessed was Flu A/CAL/7/09.

The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Secondary
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End point timeframe:

At Day 0, Day 21 and Month 7

End point values	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Subjects				
Flu A/CAL/7/09, Day 0	6	3	4	
Flu A/CAL/7/09, Day 21	13	9	12	
Flu A/CAL/7/09, Month 7	13	9	12	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroconverted subjects in terms of HI antibodies

End point title	Number of seroconverted subjects in terms of HI antibodies
End point description:	
Seroconversion (SCR) was defined as: For initially seronegative subjects (pre-vaccination titer below < 1:10), a post-vaccination titer $\geq$ 1:40. For initially seropositive subjects (pre-vaccination titer $\geq$ 1:10), at least a 4-fold increase in post-vaccination titer. The flu strain assessed was Flu A/CAL/7/09. The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.	
End point type	Secondary
End point timeframe:	
At Day 21 and Month 7	

End point values	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Subjects				
Flu A/CAL/7/09, Day 21	13	8	9	
Flu A/CAL/7/09, Month 7	12	7	10	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of seroprotected subjects for HI antibodies

End point title	Number of seroprotected subjects for HI antibodies
End point description:	
A seroprotected subject was defined as a vaccinated subject with a serum HI titer $\geq$ 1:40, which is usually accepted as indicating protection. The flu strain assessed was Flu A/CAL/7/09. The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against	

H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Secondary
End point timeframe:	
At Day 0, Day 21 and Month 7	

End point values	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Subjects				
Flu A/CAL/7/09, Day 0	6	2	2	
Flu A/CAL/7/09, Day 21	13	9	9	
Flu A/CAL/7/09, Month 7	13	8	11	

Statistical analyses

No statistical analyses for this end point

Secondary: Geometric mean fold increase (GMFR) for serum HI antibody titer

End point title	Geometric mean fold increase (GMFR) for serum HI antibody titer
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End point description:

GMFR, also called seroconversion factor (SCF), was defined as the fold increase in serum HI geometric mean titers (GMTs) post-vaccination compared to pre-vaccination. The flu strain assessed was Flu A/CAL/7/09.

The analysis was performed on the ATP cohort for immunogenicity, which included all evaluable subjects who received 2 doses of study vaccine and for whom assay results were available for antibodies against H1N1 antigen for any blood sample taken up to Month 7 after first vaccine dose.

End point type	Secondary
End point timeframe:	
At Day 21 and Month 7	

End point values	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	9	12	
Units: Fold increase				
geometric mean (confidence interval 95%)				
Flu A/CAL/7/09, Day 21	28.8 (16.4 to 50.5)	24.5 (10 to 59.7)	13.8 (7.2 to 26.5)	
Flu A/CAL/7/09, Month 7	10.5 (6 to 18.3)	9.3 (3.6 to 23.9)	9.5 (5.9 to 15.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any and grade 3 solicited local symptoms

End point title	Number of subjects with any and grade 3 solicited local symptoms
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End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = incidence of a particular symptom regardless of intensity grade or relationship to vaccinations. Grade 3 pain (children below 6 years of age) = cried when limb was moved/spontaneously painful. Grade 3 pain (children above 6 years of age) = significant pain at rest; pain that prevented normal everyday activities. Grade 3 redness/swelling = redness/swelling spreading beyond 50 millimeters (mm) of injection site. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with at least 1 vaccine administration documented.

End point type	Secondary
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End point timeframe:

During the 7-day (Days 0-6) post-vaccination period following each dose and across doses

End point values	GSK2340272A F1 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y3-5 Group	GSK2340272A F2 Y6-9 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	13	5	15
Units: Subjects				
Any Pain Dose 1	6	13	3	12
Grade 3 Pain Dose 1	0	0	0	0
Any Redness Dose 1	5	6	1	5
Grade 3 Redness Dose 1	0	1	0	0
Any Swelling Dose 1	4	6	1	6
Grade 3 Swelling Dose 1	0	2	0	0
Any Pain Dose 2	5	12	3	12
Grade 3 Pain Dose 2	0	1	0	0
Any Redness Dose 2	4	6	2	4
Grade 3 Redness Dose 2	0	1	0	0
Any Swelling Dose 2	5	9	1	5
Grade 3 Swelling Dose 2	0	2	0	1
Any Pain Across doses	6	13	4	13
Grade 3 Pain Across doses	0	1	0	0
Any Redness Across doses	5	9	3	8
Grade 3 Redness Across doses	0	1	0	0
Any Swelling Across doses	6	10	2	8
Grade 3 Swelling Across doses	0	3	0	1

End point values	GSK2340272A F3 Y3-5 Group	GSK2340272A F3 Y6-9 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	12		
Units: Subjects				
Any Pain Dose 1	1	6		
Grade 3 Pain Dose 1	0	0		
Any Redness Dose 1	2	4		
Grade 3 Redness Dose 1	0	0		
Any Swelling Dose 1	1	2		
Grade 3 Swelling Dose 1	0	0		
Any Pain Dose 2	1	4		
Grade 3 Pain Dose 2	0	0		
Any Redness Dose 2	3	4		
Grade 3 Redness Dose 2	1	0		
Any Swelling Dose 2	2	3		
Grade 3 Swelling Dose 2	1	0		
Any Pain Across doses	2	6		
Grade 3 Pain Across doses	0	0		
Any Redness Across doses	3	7		
Grade 3 Redness Across doses	1	0		
Any Swelling Across doses	3	3		
Grade 3 Swelling Across doses	1	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms

End point title	Number of subjects with any, grade 3 and related solicited general symptoms
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End point description:

Assessed solicited general symptoms were drowsiness, irritability, loss of appetite and fever [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)]. Any = incidence of a particular symptom regardless of intensity grade or relationship to vaccinations. Grade 3 drowsiness = drowsiness which prevented normal everyday activities. Grade 3 irritability = crying that could not be comforted/prevented normal activity. Grade 3 loss of appetite = not eating at all. Grade 3 fever = fever > 39.0 °C. Related = symptom assessed by the investigator as causally related to the vaccination. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with at least 1 vaccine administration documented.

End point type	Secondary
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End point timeframe:

During the 7-day (Days 0-6) post-vaccination period following each dose and across doses

End point values	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	7	5	6	
Units: Subjects				
Any Drowsiness Dose 1	3	2	3	
Grade 3 Drowsiness Dose 1	0	0	0	
Related Drowsiness Dose 1	0	0	0	
Any Irritability Dose 1	2	2	0	
Grade 3 Irritability Dose 1	0	0	0	
Related Irritability Dose 1	0	0	0	
Any Loss of appetite Dose 1	2	0	0	
Grade 3 Loss of appetite Dose 1	0	0	0	
Related Loss of appetite Dose 1	0	0	0	
Any Temperature Dose 1	2	0	1	
Grade 3 Temperature Dose 1	2	0	0	
Related Temperature Dose 1	1	0	0	
Any Drowsiness Dose 2	1	0	2	
Grade 3 Drowsiness Dose 2	0	0	0	
Related Drowsiness Dose 2	0	0	0	
Any Irritability Dose 2	1	1	0	
Grade 3 Irritability Dose 2	0	0	0	
Related Irritability Dose 2	1	0	0	
Any Loss of appetite Dose 2	1	0	0	
Grade 3 Loss of appetite Dose 2	0	0	0	
Related Loss of appetite Dose 2	0	0	0	
Any Temperature Dose 2	0	0	1	
Grade 3 Temperature Dose 2	0	0	0	
Related Temperature Dose 2	0	0	0	
Any Drowsiness Across doses	4	2	3	
Grade 3 Drowsiness Across doses	0	0	0	
Related Drowsiness Across doses	0	0	0	
Any Irritability Across doses	3	2	0	
Grade 3 Irritability Across doses	0	0	0	
Related Irritability Across doses	1	0	0	
Any Loss of appetite Across doses	3	0	0	
Grade 3 Loss of appetite Across doses	0	0	0	
Related Loss of appetite Across doses	0	0	0	
Any Temperature Across doses	2	0	2	
Grade 3 Temperature Across doses	2	0	0	
Related Temperature Across doses	1	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, grade 3 and related solicited general symptoms

End point title	Number of subjects with any, grade 3 and related solicited
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End point description:

Assessed solicited general symptoms were fatigue, gastrointestinal, headache and temperature [defined as axillary temperature equal to or above 37.5 degrees Celsius (°C)]. Any = incidence of a particular symptom regardless of intensity grade or relationship to vaccinations. Grade 3 = symptom which prevented normal everyday activity. Related = symptom assessed by the investigator as causally related to the vaccination. Grade 3 fever = fever > 39.0 °C.

The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with at least 1 vaccine administration documented.

End point type	Secondary
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End point timeframe:

During the 7-day (Days 0-6) post-vaccination period following each dose and across doses

End point values	GSK2340272A Formulation 1 Group	GSK2340272A Formulation 2 Group	GSK2340272A Formulation 3 Group	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	13	15	12	
Units: Subjects				
Any Fatigue, D1	5	5	8	
Grade 3 Fatigue, D1	0	0	0	
Related Fatigue, D1	3	0	2	
Any Gastrointestinal, D1	3	2	2	
Grade 3 Gastrointestinal, D1	0	0	0	
Related Gastrointestinal, D1	1	0	0	
Any Headache, D1	7	5	5	
Grade 3 Headache, D1	0	0	0	
Related Headache, D1	1	0	1	
Any Temperature/(Axillary), D1	1	1	1	
Grade 3 Temperature/(Axillary), D1	0	0	0	
Related Temperature/(Axillary), D1	1	0	1	
Any Fatigue, D2	6	7	1	
Grade 3 Fatigue, D2	0	2	0	
Related Fatigue, D2	2	2	1	
Any Gastrointestinal, D2	4	3	0	
Grade 3 Gastrointestinal, D2	0	0	0	
Related Gastrointestinal, D2	2	0	0	
Any Headache, D2	6	9	0	
Grade 3 Headache, D2	1	1	0	
Related Headache, D2	3	2	0	
Any Temperature/(Axillary), D2	4	1	0	
Grade 3 Temperature/(Axillary), D2	0	0	0	
Related Temperature/(Axillary), D2	3	1	0	
Any Fatigue, Across doses	6	9	8	
Grade 3 Fatigue, Across doses	0	2	0	
Related Fatigue, Across doses	3	2	3	
Any Gastrointestinal, Across doses	4	3	2	
Grade 3 Gastrointestinal, Across doses	0	0	0	
Related Gastrointestinal, Across doses	2	0	0	
Any Headache, Across doses	10	9	5	
Grade 3 Headache, Across doses	1	1	0	

Related Headache, Across doses	3	2	1	
Any Temperature/(Axillary), Across doses	4	2	1	
Grade 3 Temperature/(Axillary), Across doses	0	0	0	
Related Temperature/(Axillary), Across doses	3	1	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with medically-attended events (MAEs)

End point title	Number of subjects with medically-attended events (MAEs)
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End point description:

MAEs were defined as events for which the subject received medical attention defined as hospitalization, an emergency room visit, or a visit to or from medical personnel (medical doctor) for any reason. Any MAE(s) = Occurrence of any MAE(s) regardless of intensity grade or relation to vaccination. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with at least 1 vaccine administration documented.

End point type	Secondary
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End point timeframe:

During the entire study period (from Month 0 up to Month 12)

End point values	GSK2340272A F1 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y3-5 Group	GSK2340272A F2 Y6-9 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	13	5	15
Units: Subjects				
Any MAEs	4	11	5	11

End point values	GSK2340272A F3 Y3-5 Group	GSK2340272A F3 Y6-9 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	12		
Units: Subjects				
Any MAEs	6	10		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with adverse events of specific interest (AESIs)/potential immune-mediated disease (pIMDs)

End point title	Number of subjects with adverse events of specific interest (AESIs)/potential immune-mediated disease (pIMDs)
End point description:	
Adverse events of specific interest (AESI) were defined as AEs including autoimmune diseases and other mediated inflammatory disorders and assessed by the investigator as specific to the treatment administration. Potential immune-mediated diseases (pIMDs) are a subset of AEs that include autoimmune diseases and other inflammatory and/or neurologic disorders of interest which may or may not have an autoimmune aetiology. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with at least 1 vaccine administration documented.	
End point type	Secondary
End point timeframe:	
During the entire study period (from Month 0 up to Month 12)	

End point values	GSK2340272A F1 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y3-5 Group	GSK2340272A F2 Y6-9 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	13	5	15
Units: Subjects				
Any AESI(s)/pIMD(s)	0	0	0	0

End point values	GSK2340272A F3 Y3-5 Group	GSK2340272A F3 Y6-9 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	12		
Units: Subjects				
Any AESI(s)/pIMD(s)	0	0		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with unsolicited adverse events (AEs)
End point description:	
An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with at least 1 vaccine administration documented.	
End point type	Secondary
End point timeframe:	
Within the 42-day (Days 0-41) post-vaccination period	

End point values	GSK2340272A F1 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y3-5 Group	GSK2340272A F2 Y6-9 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	13	5	15
Units: Subjects				
Any AEs	1	2	0	2
Grade 3 AEs	0	1	0	0
Related AEs	0	1	0	0

End point values	GSK2340272A F3 Y3-5 Group	GSK2340272A F3 Y6-9 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	12		
Units: Subjects				
Any AEs	2	2		
Grade 3 AEs	0	0		
Related AEs	0	0		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects with serious adverse events (SAEs)
End point description:	
Serious adverse events (SAEs) assessed include medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/incapacity. The analysis was performed on the Total Vaccinated Cohort, which included all vaccinated subjects with at least 1 vaccine administration documented.	
End point type	Secondary
End point timeframe:	
During the entire study period (from Month 0 to Month 12)	

End point values	GSK2340272A F1 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y3-5 Group	GSK2340272A F2 Y6-9 Group
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	13	5	15
Units: Subjects				
Any SAEs	0	1	1	1

End point values	GSK2340272A F3 Y3-5 Group	GSK2340272A F3 Y6-9 Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	12		
Units: Subjects				
Any SAEs	0	1		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: 7-day follow-up period after each vaccination;

Unsolicited adverse events (AEs): during a 21-day follow-up period after each vaccination;

Serious adverse events (SAEs): during the entire study period;

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	14.0
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Reporting groups

Reporting group title	GSK2340272A F2 Y3-5 Group
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Reporting group description:

Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 2 (F2) in the deltoid region of the arm, according to a 0-21 day schedule.

Reporting group title	GSK2340272A F1 Y6-9 Group
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Reporting group description:

Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 1 (F1) in the deltoid region of the arm, according to a 0-21 day schedule.

Reporting group title	GSK2340272A F2 Y6-9 Group
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Reporting group description:

Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 2 (F2) in the deltoid region of the arm, according to a 0-21 day schedule.

Reporting group title	GSK2340272A F1 Y3-5 Group
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Reporting group description:

Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 1 (F1) in the deltoid region of the arm, according to a 0-21 day schedule.

Reporting group title	GSK2340272A F3 Y6-9 Group
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Reporting group description:

Healthy male or female children, between 6 and 9 years of age (Y6-9) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 3 (F3) in the deltoid region of the arm, according to a 0-21 day schedule.

Reporting group title	GSK2340272A F3 Y3-5 Group
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Reporting group description:

Healthy male or female children, between 3 and 5 years of age (Y3-5) at the time of first study vaccination, who intramuscularly received 2 doses of GSK2340272A vaccine formulation 3 (F3) in the deltoid region of the arm, according to a 0-21 day schedule.

Serious adverse events	GSK2340272A F2 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y6-9 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 5 (20.00%)	1 / 13 (7.69%)	1 / 15 (6.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Injury, poisoning and procedural complications			
Muscle injury			
subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 15 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acute tonsillitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	GSK2340272A F1 Y3-5 Group	GSK2340272A F3 Y6-9 Group	GSK2340272A F3 Y3-5 Group
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0

Injury, poisoning and procedural complications			
Muscle injury			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 6 (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
Contusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 6 (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
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acute tonsillitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 6 (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
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 6 (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

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

Non-serious adverse events	GSK2340272A F2 Y3-5 Group	GSK2340272A F1 Y6-9 Group	GSK2340272A F2 Y6-9 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 5 (80.00%)	13 / 13 (100.00%)	15 / 15 (100.00%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 5 (80.00%)	13 / 13 (100.00%)	13 / 15 (86.67%)
occurrences (all)	4	13	13
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 5 (60.00%)	9 / 13 (69.23%)	8 / 15 (53.33%)
occurrences (all)	3	9	8
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 5 (40.00%)	10 / 13 (76.92%)	8 / 15 (53.33%)
occurrences (all)	2	10	8
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 5 (40.00%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 5 (40.00%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	2	0	0
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Temperature/(Axillary)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Fatigue			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 5 (0.00%)	6 / 13 (46.15%)	9 / 15 (60.00%)
occurrences (all)	0	6	9
Gastrointestinal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 5 (0.00%)	4 / 13 (30.77%)	3 / 15 (20.00%)
occurrences (all)	0	4	3
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 5 (0.00%)	10 / 13 (76.92%)	9 / 15 (60.00%)
occurrences (all)	0	10	9
Eye disorders			
Conjunctivitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	4 / 13 (30.77%)	2 / 15 (13.33%)
occurrences (all)	0	4	2
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	2 / 5 (40.00%)	0 / 13 (0.00%)	1 / 15 (6.67%)
occurrences (all)	2	0	1
Tonsillitis			
subjects affected / exposed	1 / 5 (20.00%)	4 / 13 (30.77%)	2 / 15 (13.33%)
occurrences (all)	1	4	2
Tracheitis			

subjects affected / exposed	1 / 5 (20.00%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 13 (0.00%)	0 / 15 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 13 (7.69%)	0 / 15 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	GSK2340272A F1 Y3-5 Group	GSK2340272A F3 Y6-9 Group	GSK2340272A F3 Y3-5 Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	11 / 12 (91.67%)	6 / 6 (100.00%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 7 (85.71%)	6 / 12 (50.00%)	2 / 6 (33.33%)
occurrences (all)	6	6	2
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 7 (71.43%)	7 / 12 (58.33%)	3 / 6 (50.00%)
occurrences (all)	5	7	3
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 7 (85.71%)	3 / 12 (25.00%)	3 / 6 (50.00%)
occurrences (all)	6	3	3
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 7 (57.14%)	0 / 12 (0.00%)	3 / 6 (50.00%)
occurrences (all)	4	0	3
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 7 (42.86%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Loss of appetite			
alternative assessment type: Systematic			

subjects affected / exposed occurrences (all)	3 / 7 (42.86%) 3	0 / 12 (0.00%) 0	0 / 6 (0.00%) 0
Temperature/(Axillary) alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	0 / 12 (0.00%) 0	2 / 6 (33.33%) 2
Fatigue alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	8 / 12 (66.67%) 8	0 / 6 (0.00%) 0
Gastrointestinal alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	2 / 12 (16.67%) 2	0 / 6 (0.00%) 0
Headache alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	5 / 12 (41.67%) 5	0 / 6 (0.00%) 0
Eye disorders Conjunctivitis subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	1 / 6 (16.67%) 1
Gastrointestinal disorders Vomiting subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 12 (8.33%) 1	0 / 6 (0.00%) 0
Diarrhoea subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 12 (8.33%) 1	0 / 6 (0.00%) 0
Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 7 (28.57%) 2	1 / 12 (8.33%) 1	4 / 6 (66.67%) 4
Otitis media subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	0 / 12 (0.00%) 0	2 / 6 (33.33%) 2

Rhinitis			
subjects affected / exposed	1 / 7 (14.29%)	2 / 12 (16.67%)	1 / 6 (16.67%)
occurrences (all)	1	2	1
Tonsillitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	1 / 7 (14.29%)	1 / 12 (8.33%)	2 / 6 (33.33%)
occurrences (all)	1	1	2
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 12 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 12 (8.33%)	0 / 6 (0.00%)
occurrences (all)	0	1	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