



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	v1
This version publication date	19 April 2016
First version publication date	23 May 2015

Trial information

Trial identification

Sponsor protocol code	113810
-----------------------	--------

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
-------------------	---

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
----------------------------	-----------------

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 Formulation 1 Group 3-5 Years

Arm description:

Subjects received 2 doses of Flu vaccine formulation 1 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.

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 Formulation 1 Group 6-9 Years
------------------	---

Arm description:

Subjects received 2 doses of Flu vaccine formulation 1 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.

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 Formulation 2 Group 3-5 Years
Arm description:	
Subjects received 2 doses of Flu vaccine formulation 2 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.	
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 Formulation 2 Group 6-9 Years
Arm description:	
Subjects received 2 doses of Flu vaccine formulation 2 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.	
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 Formulation 3 Group 3-5 Years
Arm description:	
Subjects received 2 doses of Flu vaccine formulation 3 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.	
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 Formulation 3 Group 6-9 Years
Arm description:	
Subjects received 2 doses of Flu vaccine formulation 3 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.	
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.

Number of subjects in period 1^[1]	GSK2340272A Formulation 1 Group 3-5 Years	GSK2340272A Formulation 1 Group 6-9 Years	GSK2340272A Formulation 2 Group 3-5 Years
Started	7	13	5
Completed	7	13	5

Number of subjects in period 1^[1]	GSK2340272A Formulation 2 Group 6-9 Years	GSK2340272A Formulation 3 Group 3-5 Years	GSK2340272A Formulation 3 Group 6-9 Years
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 administrated although a subject number was allocated.

Baseline characteristics

Reporting groups

Reporting group title	GSK2340272A Formulation 1 Group 3-5 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 1 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.	
Reporting group title	GSK2340272A Formulation 1 Group 6-9 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 1 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.	
Reporting group title	GSK2340272A Formulation 2 Group 3-5 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 2 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.	
Reporting group title	GSK2340272A Formulation 2 Group 6-9 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 2 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.	
Reporting group title	GSK2340272A Formulation 3 Group 3-5 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 3 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.	
Reporting group title	GSK2340272A Formulation 3 Group 6-9 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 3 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.	

Reporting group values	GSK2340272A Formulation 1 Group 3-5 Years	GSK2340272A Formulation 1 Group 6-9 Years	GSK2340272A Formulation 2 Group 3-5 Years
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 Formulation 2 Group 6-9 Years	GSK2340272A Formulation 3 Group 3-5 Years	GSK2340272A Formulation 3 Group 6-9 Years
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 standard deviation	7.3 ± 0.9	3.8 ± 0.98	7.6 ± 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 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	0 0 0 0 0 0 0 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 Formulation 1 Group 3-5 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 1 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.	
Reporting group title	GSK2340272A Formulation 1 Group 6-9 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 1 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.	
Reporting group title	GSK2340272A Formulation 2 Group 3-5 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 2 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.	
Reporting group title	GSK2340272A Formulation 2 Group 6-9 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 2 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.	
Reporting group title	GSK2340272A Formulation 3 Group 3-5 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 3 according to a 0, 21-day schedule. Subjects aged between and including 3 years to 5 years.	
Reporting group title	GSK2340272A Formulation 3 Group 6-9 Years
Reporting group description: Subjects received 2 doses of Flu vaccine formulation 3 according to a 0, 21-day schedule. Subjects aged between and including 6 years to 9 years.	
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 Fluarix vaccine containing H1N1 strain.

End point title	Haemagglutination inhibition (HI) antibody titers against Fluarix vaccine containing H1N1 strain. ^[1]
End point description:	
End point type	Primary
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 subjects with HI antibody titers $\geq$ 1:10.

End point title	Number of subjects with HI antibody titers $\geq$ 1:10. ^[2]
-----------------	--

End point description:

End point type	Primary
----------------	---------

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]
-----------------	--

End point description:

End point type	Primary
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]
End point description:	

End point type	Primary
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 for serum HI antibody titer.

End point title	Geometric mean fold increase for serum HI antibody titer. ^[5]
-----------------	--

End point description:

End point type	Primary
----------------	---------

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 Fluarix vaccine containing H1N1 strain

End point title	HI antibody titers against Fluarix vaccine containing H1N1 strain
-----------------	---

End point description:

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: 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 subjects with anti-HIs antibody concentrations $\geq$ 1:10.

End point title	Number of subjects with anti-HIs antibody concentrations $\geq$ 1:10.
-----------------	---

End point description:

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 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:

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:

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 for serum HI antibody titer.

End point title Geometric mean fold increase for serum HI antibody titer.

End point description:

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 solicited local symptoms.

End point title	Number of subjects with solicited local symptoms.
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

During a 7-day follow- up period, i.e., day of vaccination and 6 subsequent days after each vaccination.

End point values	GSK2340272A Formulation 1 Group 3-5 Years	GSK2340272A Formulation 1 Group 6-9 Years	GSK2340272A Formulation 2 Group 3-5 Years	GSK2340272A Formulation 2 Group 6-9 Years
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 Formulation 3 Group 3-5 Years	GSK2340272A Formulation 3 Group 6-9 Years		
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 solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

During a 7-day follow-up period, i.e., day of vaccination and 6 subsequent days after each vaccination, subjects aged between and including 3 to 5 years.

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 solicited general symptoms.

End point title	Number of subjects with solicited general symptoms.
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

During a 7-day follow-up period, i.e., day of vaccination and 6 subsequent days after each vaccination, subjects aged between and including 6 to 9 years.

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).
-----------------	---

End point description:

End point type	Secondary
----------------	-----------

End point timeframe:

During the entire study period.

End point values	GSK2340272A Formulation 1 Group 3-5 Years	GSK2340272A Formulation 1 Group 6-9 Years	GSK2340272A Formulation 2 Group 3-5 Years	GSK2340272A Formulation 2 Group 6-9 Years
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 Formulation 3 Group 3-5 Years	GSK2340272A Formulation 3 Group 6-9 Years		
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:

End point type	Secondary
----------------	-----------

End point timeframe:

During the entire study period.

End point values	GSK2340272A Formulation 1 Group 3-5 Years	GSK2340272A Formulation 1 Group 6-9 Years	GSK2340272A Formulation 2 Group 3-5 Years	GSK2340272A Formulation 2 Group 6-9 Years
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 Formulation 3 Group 3-5 Years	GSK2340272A Formulation 3 Group 6-9 Years		
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:

End point type	Secondary
----------------	-----------

End point timeframe:

Within the 42-day (Days 0-41) post-vaccination period.

End point values	GSK2340272A Formulation 1 Group 3-5 Years	GSK2340272A Formulation 1 Group 6-9 Years	GSK2340272A Formulation 2 Group 3-5 Years	GSK2340272A Formulation 2 Group 6-9 Years
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 Formulation 3 Group 3-5 Years	GSK2340272A Formulation 3 Group 6-9 Years		
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:

End point type	Secondary
----------------	-----------

End point timeframe:

During the entire study period.

End point values	GSK2340272A Formulation 1 Group 3-5 Years	GSK2340272A Formulation 1 Group 6-9 Years	GSK2340272A Formulation 2 Group 3-5 Years	GSK2340272A Formulation 2 Group 6-9 Years
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 Formulation 3 Group 3-5 Years	GSK2340272A Formulation 3 Group 6-9 Years		
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
-----------------	----------------

Dictionary used

Dictionary name	MedDRA
-----------------	--------

Dictionary version	14.0
--------------------	------

Reporting groups

Reporting group title	Flu F1 Group 3-5 Years
-----------------------	------------------------

Reporting group description: -	
--------------------------------	--

Reporting group title	Flu F1 Group 6-9 Years
-----------------------	------------------------

Reporting group description: -	
--------------------------------	--

Reporting group title	Flu F2 Group 3-5 Years
-----------------------	------------------------

Reporting group description: -	
--------------------------------	--

Reporting group title	Flu F2 Group 6-9 Years
-----------------------	------------------------

Reporting group description: -	
--------------------------------	--

Reporting group title	Flu F3 Group 3-5 Years
-----------------------	------------------------

Reporting group description: -	
--------------------------------	--

Reporting group title	Flu F3 Group 6-9 Years
-----------------------	------------------------

Reporting group description: -	
--------------------------------	--

Serious adverse events	Flu F1 Group 3-5 Years	Flu F1 Group 6-9 Years	Flu F2 Group 3-5 Years
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 7 (0.00%)	1 / 13 (7.69%)	1 / 5 (20.00%)
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%)	1 / 13 (7.69%)	0 / 5 (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 / 7 (0.00%)	0 / 13 (0.00%)	0 / 5 (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 / 7 (0.00%)	0 / 13 (0.00%)	0 / 5 (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 / 13 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Acute tonsillitis			
subjects affected / exposed	0 / 7 (0.00%)	1 / 13 (7.69%)	0 / 5 (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 / 7 (0.00%)	1 / 13 (7.69%)	0 / 5 (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	Flu F2 Group 6-9 Years	Flu F3 Group 3-5 Years	Flu F3 Group 6-9 Years
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 15 (6.67%)	0 / 6 (0.00%)	1 / 12 (8.33%)
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 / 15 (0.00%)	0 / 6 (0.00%)	0 / 12 (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 / 15 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Adenoidal hypertrophy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 6 (0.00%)	0 / 12 (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 / 15 (0.00%)	0 / 6 (0.00%)	0 / 12 (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 / 15 (0.00%)	0 / 6 (0.00%)	0 / 12 (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	Flu F1 Group 3-5 Years	Flu F1 Group 6-9 Years	Flu F2 Group 3-5 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 7 (85.71%)	13 / 13 (100.00%)	5 / 5 (100.00%)
General disorders and administration site conditions			
Pain			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 7 (85.71%)	13 / 13 (100.00%)	4 / 5 (80.00%)
occurrences (all)	6	13	4
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 7 (71.43%)	9 / 13 (69.23%)	3 / 5 (60.00%)
occurrences (all)	5	9	3
Swelling			

alternative assessment type: Systematic			
subjects affected / exposed	6 / 7 (85.71%)	10 / 13 (76.92%)	2 / 5 (40.00%)
occurrences (all)	6	10	2
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 7 (57.14%)	0 / 13 (0.00%)	2 / 5 (40.00%)
occurrences (all)	4	0	2
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 7 (42.86%)	0 / 13 (0.00%)	2 / 5 (40.00%)
occurrences (all)	3	0	2
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 7 (42.86%)	0 / 13 (0.00%)	0 / 5 (0.00%)
occurrences (all)	3	0	0
Temperature/(Axillary)			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 7 (28.57%)	0 / 13 (0.00%)	0 / 5 (0.00%)
occurrences (all)	2	0	0
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 7 (0.00%)	6 / 13 (46.15%)	0 / 5 (0.00%)
occurrences (all)	0	6	0
Gastrointestinal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 7 (0.00%)	4 / 13 (30.77%)	0 / 5 (0.00%)
occurrences (all)	0	4	0
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 7 (0.00%)	10 / 13 (76.92%)	0 / 5 (0.00%)
occurrences (all)	0	10	0
Eye disorders			
Conjunctivitis			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0	1 / 13 (7.69%) 1	0 / 5 (0.00%) 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 7 (0.00%)	0 / 13 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 13 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 7 (28.57%)	4 / 13 (30.77%)	0 / 5 (0.00%)
occurrences (all)	2	4	0
Otitis media			
subjects affected / exposed	0 / 7 (0.00%)	1 / 13 (7.69%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 13 (0.00%)	2 / 5 (40.00%)
occurrences (all)	1	0	2
Tonsillitis			
subjects affected / exposed	0 / 7 (0.00%)	4 / 13 (30.77%)	1 / 5 (20.00%)
occurrences (all)	0	4	1
Tracheitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 13 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 13 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 7 (0.00%)	1 / 13 (7.69%)	0 / 5 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Flu F2 Group 6-9 Years	Flu F3 Group 3-5 Years	Flu F3 Group 6-9 Years
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 15 (86.67%)	6 / 6 (100.00%)	10 / 12 (83.33%)
General disorders and administration site conditions			

Pain			
alternative assessment type: Systematic			
subjects affected / exposed	13 / 15 (86.67%)	2 / 6 (33.33%)	6 / 12 (50.00%)
occurrences (all)	13	2	6
Redness			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 15 (53.33%)	3 / 6 (50.00%)	7 / 12 (58.33%)
occurrences (all)	8	3	7
Swelling			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 15 (53.33%)	3 / 6 (50.00%)	3 / 12 (25.00%)
occurrences (all)	8	3	3
Drowsiness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	3 / 6 (50.00%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
Irritability			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Loss of appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 6 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Temperature/(Axillary)			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 15 (0.00%)	2 / 6 (33.33%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 15 (60.00%)	0 / 6 (0.00%)	8 / 12 (66.67%)
occurrences (all)	9	0	8
Gastrointestinal			
alternative assessment type: Systematic			

subjects affected / exposed occurrences (all)	3 / 15 (20.00%) 3	0 / 6 (0.00%) 0	2 / 12 (16.67%) 2
Headache alternative assessment type: Systematic			
subjects affected / exposed occurrences (all)	9 / 15 (60.00%) 9	0 / 6 (0.00%) 0	5 / 12 (41.67%) 5
Eye disorders			
Conjunctivitis			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 6 (16.67%) 1	0 / 12 (0.00%) 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	0 / 6 (0.00%) 0	1 / 12 (8.33%) 1
Diarrhoea			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	0 / 6 (0.00%) 0	1 / 12 (8.33%) 1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	4 / 6 (66.67%) 4	1 / 12 (8.33%) 1
Otitis media			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	2 / 6 (33.33%) 2	0 / 12 (0.00%) 0
Rhinitis			
subjects affected / exposed occurrences (all)	1 / 15 (6.67%) 1	1 / 6 (16.67%) 1	2 / 12 (16.67%) 2
Tonsillitis			
subjects affected / exposed occurrences (all)	2 / 15 (13.33%) 2	0 / 6 (0.00%) 0	0 / 12 (0.00%) 0
Tracheitis			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	2 / 6 (33.33%) 2	1 / 12 (8.33%) 1
Upper respiratory tract infection			
subjects affected / exposed occurrences (all)	0 / 15 (0.00%) 0	1 / 6 (16.67%) 1	0 / 12 (0.00%) 0

Viral infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 6 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported