Clinical trial results:
A Phase II, non-randomised, open-label study to evaluate the safety and immunogenicity of the adjuvanted (pre-) pandemic H5N1 influenza candidate vaccine following a heterologous prime-boost schedule (six months apart) in children aged 6 to 35 months

Summary

EudraCT number	2011-004734-33
Trial protocol	Outside EU/EEA
Global end of trial date	02 November 2012

Results information

Result version number	v3 (current)
This version publication date	02 August 2023
First version publication date	24 May 2015
Version creation reason	• Correction of full data set Corrections in safety section and age stratification added for immunogenicity endpoints.

Trial information

Trial identification

Sponsor protocol code	109825

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01323946
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 Disclosure Advisor, GlaxoSmithKline Biologicals, 044 2089904466, GSKClinicalSupportHD@gsk.com
Scientific contact	Clinical Disclosure Advisor, GlaxoSmithKline Biologicals, 044 2089904466, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000160-PIP01-07
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	14 February 2013
Is this the analysis of the primary completion data?	Yes
Primary completion date	22 June 2012
Global end of trial reached?	Yes
Global end of trial date	02 November 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess whether a heterologous booster dose of H5N1 (A/turkey/Turkey/1/2005) haemagglutinin (HA) given 6 months following a 2-dose primary vaccination series with H5N1 (A/Indonesia/05/2005) HA elicits an antibody response that meets the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) guidance targets for pre-pandemic vaccine seroconversion rate (SCR), seroprotection rate (SPR) and mean geometric increase (MGI) based on haemagglutination inhibition (HI) responses to A/turkey/Turkey/1/2005 (H5N1) ten days following booster vaccination.

Protection of trial subjects:

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	18 April 2011
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	Singapore: 84
Country: Number of subjects enrolled	Australia: 29
Worldwide total number of subjects	113
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	80
Children (2-11 years)	33

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:

During the screening the following steps occurred: check for inclusion/exclusion criteria, contraindications/precautions, medical history of the subjects and signing informed consent forms.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK1562902A 6 to 12 M Group

Arm description:

Subjects between 6 and 12 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.

Arm type	Experimental
Investigational medicinal product name	GSK1562902A vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

The vaccine was administered intramuscularly in the anterolateral thigh.

Arm title	GSK1562902A 12 to 24 M Group

Arm description:

Subjects between 12 and 24 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.

Arm type	Experimental
Investigational medicinal product name	GSK1562902A vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

Arm title	GSK1562902A 24 to 36 M Group

Arm description:

Subjects between 24 and 36 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.

Arm type	Experimental

Investigational medicinal product name	GSK1562902A vaccine
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intramuscular use

Dosage and administration details:

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

Number of subjects in period 1	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group
Started	46	34	33
Completed	43	31	33
Not completed	3	3	0
Consent withdrawn by subject	3	3	-

Baseline characteristics

Reporting groups	
Reporting group title	GSK1562902A 6 to 12 M Group
Reporting group description:	
Subjects between 6 and 12 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.	
Reporting group title	GSK1562902A 12 to 24 M Group
Reporting group description:	
Subjects between 12 and 24 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.	
Reporting group title	GSK1562902A 24 to 36 M Group
Reporting group description:	
Subjects between 24 and 36 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.	

Reporting group values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group
Number of subjects	46	34	33
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: months			
arithmetic mean	8.3	16.1	29.6
standard deviation	± 1.56	± 3.44	± 3.38
Gender categorical Units: Subjects			
Female	25	19	19
Male	21	15	14
Race/Ethnicity characteristic Units: Subjects			
Asian-South East Asian	33	25	22
Asian-East Asian Heritage	0	1	0
White-caucasian/european heritage	12	8	9
Unspecified	1	0	2

Reporting group values	Total		
Number of subjects	113		

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: months			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	63		
Male	50		
Race/Ethnicity characteristic Units: Subjects			
Asian-South East Asian	80		
Asian-East Asian Heritage	1		
White-caucasian/european heritage	29		
Unspecified	3		

Subject analysis sets

Subject analysis set title	GSK1562902A Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.

Reporting group values	GSK1562902A Group		
Number of subjects	113		
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: months			
arithmetic mean	16.9		
standard deviation	± 9.29		
Gender categorical Units: Subjects			
Female	63		
Male	50		
Race/Ethnicity characteristic Units: Subjects			
Asian-South East Asian			
Asian-East Asian Heritage			
White-caucasian/european heritage			
Unspecified			

End points

End points reporting groups

Reporting group title	GSK1562902A 6 to 12 M Group

Reporting group description:

Subjects between 6 and 12 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.

Reporting group title	GSK1562902A 12 to 24 M Group

Reporting group description:

Subjects between 12 and 24 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.

Reporting group title	GSK1562902A 24 to 36 M Group

Reporting group description:

Subjects between 24 and 36 months of age, who received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.

Subject analysis set title	GSK1562902A Group
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received 2 primary doses of A/Indonesia/05/2005 H5N1 vaccine on Days 0 and 21 and 1 booster dose of the A/turkey/Turkey/1/2005 H5N1 vaccine on Day 182.

Primary: 1. Number of seroconverted subjects in terms of H5N1 antibodies against A/Turkey/Turkey/1/2005 H5N1 Virus Strain

End point title	1. Number of seroconverted subjects in terms of H5N1 antibodies against A/Turkey/Turkey/1/2005 H5N1 Virus Strain[1]

End point description:

A seroconverted subject is defined as a subject that had either a pre-vaccination (Day 0) titer < 1:10 and a post-vaccination titer ≥ 1:40 or a pre-vaccination titer ≥ 1:10 and at least a 4-fold increase in post-vaccination titer on Day 192.

End point type	Primary

End point timeframe:

At Day 192

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: This endpoint was descriptive, thus not statistical analysis was performed.

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	33	21	29	83
Units: Subjects				
A/turkey/Turkey/01/2005.HA [Day 192]	33	21	29	83

Statistical analyses

No statistical analyses for this end point

Primary: 2. Geometric mean of the within-subject ratios

End point title	2. Geometric mean of the within-subject ratios[2]

End point description:

HI antibody concentration against Flu A/Turk/01/05 (H5N1)

End point type	Primary

End point timeframe:

At Day 192

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: This endpoint was descriptive, thus not statistical analysis was performed.

End point values	GSK1562902A Group			
Subject group type	Subject analysis set			
Number of subjects analysed	83			
Units: Titers				
geometric mean (confidence interval 95%)				
Flu A/Turk/01/05 (H5N1).HA [Day 192]	357.7 (302.4 to 423.2)			

Statistical analyses

No statistical analyses for this end point

Primary: 3. Number of seroprotected subjects for HI antibodies

End point title	3. Number of seroprotected subjects for HI antibodies[3]

End point description:

HI antibody concentration against A/turkey/Turkey/01/2005

End point type	Primary

End point timeframe:

At Day 192

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: This endpoint was descriptive, thus not statistical analysis was performed.

End point values	GSK1562902A Group			
Subject group type	Subject analysis set			
Number of subjects analysed	83			
Units: Subjects				
A/turkey/Turkey/01/2005.HA [Day192]	83			

Statistical analyses

No statistical analyses for this end point

Secondary: 4. Hemagglutination Inhibition (HI) antibody titers against the A/indonesia/05/2005 H5N1 virus strain

End point title	4. Hemagglutination Inhibition (HI) antibody titers against the A/indonesia/05/2005 H5N1 virus strain

End point description:

Titers were presented as geometric mean titers (GMTs). Analyses were done by age stratum and overall.

End point type	Secondary

End point timeframe:

At Day 0, Day 42, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	27	32	100
Units: Titers				
geometric mean (confidence interval 95%)				
A/Indonesia/05/2005.HA [Day 0]	5 (5 to 5)	5 (5 to 5)	5 (5 to 5)	5 (5 to 5)
A/Indonesia/05/2005.HA [Day 42]	945.2 (745.8 to 1197.9)	1336.7 (990.3 to 1804.2)	1044.7 (832.6 to 1310.9)	1078.6 (935.3 to 1243.7)
A/Indonesia/05/2005.HA [Day 182]	160.0 (125.4 to 204.2)	147.3 (113.2 to 191.7)	133.7 (113.1 to 158.1)	147.2 (129.6 to 167.1)
A/Indonesia/05/2005.HA [Day 192]	2163.8 (1772.7 to 2641.4)	1534.7 (1108.1 to 2125.5)	1606.2 (1254.3 to 2056.9)	1787.6 (1552.4 to 2058.3)
A/Indonesia/05/2005.HA [Day 364]	1465.4 (1168.2 to 1838.1)	1055.8 (769.2 to 1449.1)	668.4 (505.2 to 884.2)	1043.3 (886.1 to 1228.4)

Statistical analyses

No statistical analyses for this end point

Secondary: 5. HI antibody titers against the A/Turkey/01/2005 H5N1 virus strain

End point title	5. HI antibody titers against the A/Turkey/01/2005 H5N1 virus strain

End point description:

Titers were presented as geometric mean titers (GMTs). Analyses were done by age stratum and overall.

End point type	Secondary

End point timeframe:

At Day 0, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	27	32	100
Units: Titers				
geometric mean (confidence interval 95%)				
A/turkey/Turkey/01/2005.HA [Day 0]	5.8 (5.2 to 6.5)	5.8 (4.8 to 6.9)	5.5 (4.7 to 64)	5.7 (5.2 to 6.2)
A/turkey/Turkey/01/2005.HA [Day 182]	95.7 (75.5 to 121.1)	84.1 (65.5 to 108.1)	86.1 (73.8 to 100.4)	89.3 (79.1 to 100.7)
A/turkey/Turkey/01/2005.HA [Day 192]	2454.6 (1935.7 to 3112.6)	1810.2 (1207.1 to 2714.7)	1767.4 (1403.0 to 2226.3)	2026.2 (1731.3 to 2371.3)
A/turkey/Turkey/01/2005.HA [Day 364]	1810.1 (1466.6 to 2234.0)	1263.8 (929.1 to 1718.0)	803.4 (609.7 to 1058.8)	1266.8 (1080.6 to 1485)

Statistical analyses

No statistical analyses for this end point

Secondary: 6. Number of seropositive subjects in terms of H5N1 HI antibodies against A/Indonesia/05/2005 virus strain

End point title	6. Number of seropositive subjects in terms of H5N1 HI antibodies against A/Indonesia/05/2005 virus strain

End point description:

A seropositive subject is defined as a subject with a serum H5N1 HI antibody titer >=1:10.

End point type	Secondary

End point timeframe:

At Day 0, Day 42, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	27	32	100
Units: Subjects				
A/Indonesia/05/2005.HA [Day 0]	0	0	0	0
A/Indonesia/05/2005.HA [Day 42]	32	24	29	85
A/Indonesia/05/2005.HA [Day 182]	33	24	29	83
A/Indonesia/05/2005.HA [Day 192]	33	21	29	83
A/Indonesia/05/2005.HA [Day 364]	41	27	32	100

Statistical analyses

No statistical analyses for this end point

Secondary: 7. Number of seropositive subjects in terms of H5N1 HI antibodies against A/turkey/Turkey/01/2005 virus strain

End point title	7. Number of seropositive subjects in terms of H5N1 HI antibodies against A/turkey/Turkey/01/2005 virus strain

End point description:

A seropositive subject is defined as a subject with a serum H5N1 HI antibody titer >=1:10.

End point type	Secondary

End point timeframe:

At Day 0, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	27	32	100
Units: Subjects				
A/turkey/Turkey/01/2005.HA [Day 0]	6	3	2	11
A/turkey/Turkey/01/2005.HA [Day 182]	33	21	29	83
A/turkey/Turkey/01/2005.HA [Day 192]	33	21	29	83
A/turkey/Turkey/01/2005.HA [Day 364]	41	27	32	100

Statistical analyses

No statistical analyses for this end point

Secondary: 8. Number of seroconverted subjects in terms of H5N1 HI antibodies against A/Indonesia/05/2005 virus strain

End point title	8. Number of seroconverted subjects in terms of H5N1 HI antibodies against A/Indonesia/05/2005 virus strain

End point description:

A seroconverted subject is defined as a subject who had either a pre-vaccination (Day 0) titer < 1:10 and a post-vaccination titer >=1:40, or a pre vaccination titer >=1"10 and at aleast a 4-fold increase in post-vaccination titer.

End point type	Secondary

End point timeframe:

At Day 42, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	27	32	100
Units: Subjects				
A/Indonesia/05/2005.HA [Day 42]	32	24	29	85
A/Indonesia/05/2005.HA [Day 182]	32	21	29	83
A/Indonesia/05/2005.HA [Day 192]	33	21	29	83

A/Indonesia/05/2005.HA [Day 364]	41	27	32	100

Statistical analyses

No statistical analyses for this end point

Secondary: 9. Number of seroconverted subjects in terms of H5N1 HI antibodies against A/turkey/Turkey/01/2005 virus strain

End point title	9. Number of seroconverted subjects in terms of H5N1 HI antibodies against A/turkey/Turkey/01/2005 virus strain

End point description:

A seroconverted subject is defined as a subject who had either a pre-vaccination (Day 0) titer < 1:10 and a post-vaccination titer >=1:40, or a pre vaccination titer >=1:10 and at least a 4-fold increase in post-vaccination titer. Data for Day 192 are presented under Primary Endpoints.

End point type	Secondary

End point timeframe:

At Day 182 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	26	32	99
Units: Subjects				
A/turkey/Turkey/1/2005 H5N1 (Day 182)	31	20	28	83
A/turkey/Turkey/1/2005 H5N1 (Day 364)	41	26	28	95

Statistical analyses

No statistical analyses for this end point

Secondary: 10.Number of seroprotected subjects in terms of H5N1 HI antibodies against A/Indonesia/05/2005 virus strain

End point title	10.Number of seroprotected subjects in terms of H5N1 HI antibodies against A/Indonesia/05/2005 virus strain

End point description:

A seroprotected subject is defined as a subject with a serum H5N1 HI antibody titer ≥1:40.

End point type	Secondary

End point timeframe:

At Day 0, Day 42, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	27	32	100
Units: Subjects				
A/Indonesia/05/2005 H5N1.HA [Day 0]	0	0	0	0
A/Indonesia/05/2005 H5N1.HA [Day 42]	32	24	29	85
A/Indonesia/05/2005 H5N1.HA [Day 182]	32	21	29	82
A/Indonesia/05/2005 H5N1.HA [Day 192]	33	21	29	83
A/Indonesia/05/2005 H5N1.HA [Day 364]	41	27	32	100

Statistical analyses

No statistical analyses for this end point

Secondary: 14. Number of seroconverted subjects in terms of HI antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point title	14. Number of seroconverted subjects in terms of HI antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point description:

Booster seroconversion is defined as follows: For seronegative subjects at pre-booster (Day 182), antibody titer ≥1:40 at post-booster time point(s). For seropositive subjects at pre-booster (Day 182), antibody titer at post-booster time point(s) ≥4-fold the pre-booster antibody titer.

End point type	Secondary

End point timeframe:

At Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	26	32	99
Units: Subjects				
A/turkey/Turkey/01/2005.HA [Day 192]	32	21	29	82
A/turkey/Turkey/01/2005.HA [Day 364]	41	26	28	95

Statistical analyses

No statistical analyses for this end point

Secondary: 15. Booster Factor in terms of neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point title	15. Booster Factor in terms of neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point description:

Booster Factor was defined as the geometric mean of the within-subject ratios of the post-booster vaccination reciprocal HI titre to the pre-booster (Day 182) reciprocal titer.

End point type	Secondary

End point timeframe:

At Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	26	32	99
Units: Titers				
geometric mean (confidence interval 95%)				
A/turkey/Turkey/01/2005.HA [Day 192]	25.7 (18.4 to 35.7)	21.5 (16.4 to 28.2)	20.5 (16.2 to 26.1)	22.7 (19.3 to 26.8)
A/turkey/Turkey/01/2005.HA [Day 364]	19.9 (15.2 to 26.1)	16.4 (12.6 to 21.4)	9.5 (7.2 to 12.5)	14.9 (12.6 to 17.6)

Statistical analyses

No statistical analyses for this end point

Secondary: 16.Number of seropositive subjects in terms of serum neutralizing antibodies against A/Indonesia/05/2005 H5N1 virus strain

End point title	16.Number of seropositive subjects in terms of serum neutralizing antibodies against A/Indonesia/05/2005 H5N1 virus strain

End point description:

A seropositive subject is defined as a subject with serum neutralizing antibody titers ≥ 1:28

End point type	Secondary

End point timeframe:

Day 0, Day 42, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	37	27	31	95
Units: Subjects				
Flu A/Ind/05/05 (H5N1) [Day 0]	0	0	1	1
Flu A/Ind/05/05 (H5N1) [Day 42]	24	21	25	70

Flu A/Ind/05/05 (H5N1) [Day 182]	32	21	28	81
Flu A/Ind/05/05 (H5N1) [Day 192]	33	21	29	83
Flu A/Ind/05/05 (H5N1) [Day 364]	37	27	31	95

Statistical analyses

No statistical analyses for this end point

Secondary: 17. Number of seropositive subjects in terms of serum neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point title	17. Number of seropositive subjects in terms of serum neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point description:

A seropositive subject is defined as a subject with serum neutralizing antibody titers ≥ 1:28.

End point type	Secondary

End point timeframe:

Day 0, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	37	27	31	95
Units: Subjects				
Flu A/Turk/01/05 (H5N1) [Day 0]	0	0	0	0
Flu A/Turk/01/05 (H5N1) [Day 182]	32	21	28	81
Flu A/Turk/01/05 (H5N1) [Day 192]	33	21	29	83
Flu A/Turk/01/05 (H5N1) [Day 364]	37	27	31	95

Statistical analyses

No statistical analyses for this end point

Secondary: 18. Serum neutralizing antibody titers in terms of neutralizing antibodies against A/Indonesia/05/2005 H5N1 virus strain

End point title	18. Serum neutralizing antibody titers in terms of neutralizing antibodies against A/Indonesia/05/2005 H5N1 virus strain

End point description:

Titers were presented as geometric mean titers (GMTs).

End point type	Secondary

End point timeframe:

Day 0, Day 42, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	37	27	31	95
Units: Titers				
geometric mean (confidence interval 95%)				
Flu A/Ind/05/05 (H5N1) [Day 0]	0 (0 to 0)	0 (0 to 0)	14.4 (13.6 to 15.3)	14.1 (13.9 to 14.4)
Flu A/Ind/05/05 (H5N1) [Day 42]	1785.9 (1168.6 to 2729.5)	2080.4 (1422.8 to 3041.7)	1755.2 (1191.3 to 2586.1)	1858 (1491.3 to 2315)
Flu A/Ind/05/05 (H5N1) [Day 182]	526.6 (397.1 to 698.2)	483.3 (333.1 to 701.3)	353.4 (273.7 to 456.2)	448.7 (379 to 531.2)
Flu A/Ind/05/05 (H5N1) [Day 192]	12667.0 (10522.9 to 15248.1)	11031.5 (8157.8 to 14917.5)	9883.1 (7631.9 to 12798.4)	11215.7 (9797.4 to 12839.2)
Flu A/Ind/05/05 (H5N1) [Day 364]	6420.9 (4851.0 to 8498.9)	4730.9 (3237.5 to 6913.0)	2422.9 (1674.9 to 3504.9)	4283.3 (3485.8 to 5263.2)

Statistical analyses

No statistical analyses for this end point

Secondary: 19. Serum neutralizing antibody titers in terms of neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point title	19. Serum neutralizing antibody titers in terms of neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain
End point description:	
Titers were presented as geometric mean titers (GMTs).	
End point type	Secondary
End point timeframe:	
Day 0, Day 182, Day 192 and Day 364	

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	37	27	31	95
Units: Titers				
geometric mean (confidence interval 95%)				
Flu A/Turk/01/05 (H5N1) [Day 0]	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)
Flu A/Turk/01/05 (H5N1) [Day 182]	137.5 (108.3 to 174.7)	124.9 (104.3 to 149.5)	113.2 (96.2 to 133.2)	125.4 (111.6 to 140.8)

Flu A/Turk/01/05 (H5N1) [Day 192]	7391.0 (5117.8 to 10674.0)	5464.2 (3426.9 to 8712.7)	3349.4 (2249.8 to 4986.4)	5192.9 (4101.3 to 6575.1)
Flu A/Turk/01/05 (H5N1) [Day 364]	4149.7 (3028.8 to 5685.4)	3030.8 (2036.2 to 4511.4)	1317.8 (898.4 to 1933.0)	2610.2 (2085.3 to 3267.2)

Statistical analyses

No statistical analyses for this end point

Secondary: 20. Number of subjects with a vaccine response in terms of serum neutralizing antibodies against A/Indonesia/05/2005 H5N1 virus strain

End point title	20. Number of subjects with a vaccine response in terms of serum neutralizing antibodies against A/Indonesia/05/2005 H5N1 virus strain

End point description:

Vaccine response is defined as: For initially seronegative subjects, neutralizing antibody titer ≥ 1:56 at the considered time point after vaccination For initially seropositive subjects, neutralizing antibody titer ≥ 4 fold from pre-vaccination (Day 0).

End point type	Secondary

End point timeframe:

At Day 42, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	33	25	25	83
Units: Subjects				
Flu A/Ind/05/05 (H5N1) [Day 42]	22	19	21	62
Flu A/Ind/05/05 (H5N1) [Day 182]	28	19	22	70
Flu A/Ind/05/05 (H5N1) [Day 192]	29	19	24	72
Flu A/Ind/05/05 (H5N1) [Day 364]	33	25	25	83

Statistical analyses

No statistical analyses for this end point

Secondary: 21. Number of subjects with a vaccine response in terms of serum neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point title	21. Number of subjects with a vaccine response in terms of serum neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point description:

Vaccine response is defined as: For initially seronegative subjects, neutralizing antibody titer ≥ 1:56 at the considered time point after vaccination For initially seropositive subjects, neutralizing antibody titer ≥ 4 fold from pre-vaccination (Day 0)

End point type	Secondary

End point timeframe:

At Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	33	25	25	83
Units: Subjects				
Flu A/Turk/01/05 (H5N1) Ab [Day 182]	22	17	19	58
Flu A/Turk/01/05 (H5N1) Ab [Day 192]	29	19	24	72
Flu A/Turk/01/05 (H5N1) Ab [Day 364]	33	25	25	83

Statistical analyses

No statistical analyses for this end point

Secondary: 22. Number of subjects with a booster vaccine response in terms of serum neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point title	22. Number of subjects with a booster vaccine response in terms of serum neutralizing antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point description:

Booster vaccine response is defined as: For seronegative subjects at Day 182, neutralizing antibody titers ≥ 1:56 at the considered time point after vaccination For seropositive subjects at Day 182, neutralizing antibody titers ≥ 4 fold from pre-vaccination (Day 182)

End point type	Secondary

End point timeframe:

At Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	32	24	23	79
Units: Subjects				
Flu A/Turk/01/05 (H5N1) [Day 192]	27	19	23	69
Flu A/Turk/01/05 (H5N1) [Day 364]	32	22	22	76

Statistical analyses

No statistical analyses for this end point

Secondary: 23. Number of subjects with any and Grade 3 solicited local symptoms

End point title	23. Number of subjects with any and Grade 3 solicited local symptoms

End point description:

Solicited local symptoms assigned were pain, swelling and redness. Any was defined as occurrence of any local symptom regardless of intensity grade; Grade 3 pain was defined as cried when limb was moved spontaneously painful.

End point type	Secondary

End point timeframe:

During the 7-day post-vaccination period following each dose and across doses (Day 0 - Day 7, Day 21 - Day 28, Day 182 - Day 189)

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	46	33	33	112
Units: Subjects				
Any Pain Dose 1	14	5	13	32
Grade 3 Pain Dose 1	2	0	1	3
Any Redness Dose 1	2	0	2	4
Grade 3 Redness Dose 1	0	0	0	0
Any Swelling Dose 1	1	1	1	3
Grade 3 Swelling Dose 1	0	0	0	0
Any Pain Dose 2	10	13	14	37
Grade 3 Pain Dose 2	0	0	1	1
Any Redness Dose 2	3	2	1	6
Grade 3 Redness Dose 2	0	0	0	0
Any Swelling Dose 2	2	2	0	4
Grade 3 Swelling Dose 2	0	0	0	0
Any Pain Dose 3	20	15	18	53
Grade 3 Pain Dose 3	3	1	3	7
Any Redness Dose 3	11	5	2	18
Grade 3 Redness Dose 3	0	0	0	0
Any Swelling Dose 3	5	5	1	11
Grade 3 Swelling Dose 3	0	0	0	0
Any Pain Across doses	26	19	21	66
Grade 3 Pain Across doses	4	1	5	10
Any Redness Across doses	13	6	3	22
Grade 3 Redness Across doses	0	0	0	0
Any Swelling Across doses	6	6	1	13
Grade 3 Swelling Across doses	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: 24. Number of subjects with any, Grade 3 and related solicited general

symptoms

End point title	24. Number of subjects with any, Grade 3 and related solicited general symptoms

End point description:

Solicited general symptoms assessed were diarrhoea/ vomiting, drowsiness, irritability/ fussiness, loss of appetite, fever (axillary). Any= occurrence of any general symptom regardless of intensity grade and relationship to the vaccine. Irritability/ fussiness grade 3=crying that could not be comforted/ prevented normal activity; Drowsiness grade 3= drowsiness that prevented normal activity; Loss of appetite grade 3= did not eat at all; Diarrhoea/ vomiting grade 3= diarrhoea/ vomiting that prevented normal activity; Related= general symptom assessed by the investigator as causally related to the study vaccination.

End point type	Secondary

End point timeframe:

During the 7-day post-vaccination period following each dose and across doses (Day 0 - Day 7, Day 21 - Day 28, Day 182 - Day 189)

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	46	33	33	112
Units: Subjects				
Any Diarrhoea/vomiting Dose 1	10	6	3	19
Grade 3 Diarrhoea/vomiting Dose 1	1	1	0	2
Related Diarrhoea/vomiting Dose 1	6	1	2	9
Any Drowsiness Dose 1	10	9	5	24
Grade 3 Drowsiness Dose 1	1	0	0	1
Related Drowsiness Dose 1	8	7	5	20
Any Irritability/fussiness Dose 1	21	14	9	44
Grade 3 Irritability/fussiness Dose 1	3	0	0	3
Related Irritability/fussiness Dose 1	19	10	8	37
Any Loss of appetite Dose 1	9	12	6	27
Grade 3 Loss of appetite Dose 1	0	1	0	1
Related Loss of appetite Dose 1	5	8	5	18
Any Fever (Axillary) Dose 1	4	6	4	14
Grade 3 Fever (Axillary) Dose 1	0	2	0	2
Related Fever (Axillary) Dose 1	3	5	3	11
Any Diarrhoea/vomiting Dose 2	8	3	2	13
Grade 3 Diarrhoea/vomiting Dose 2	0	0	0	0
Related Diarrhoea/vomiting Dose 2	7	2	1	10
Any Drowsiness Dose 2	8	12	7	27
Grade 3 Drowsiness Dose 2	1	1	1	3
Related Drowsiness Dose 2	8	10	7	25
Any Irritability/fussiness Dose 2	14	17	10	41
Grade 3 Irritability/fussiness Dose 2	1	3	0	4
Related Irritability/fussiness Dose 2	13	15	10	38
Any Loss of appetite Dose 2	8	6	9	23
Grade 3 Loss of appetite Dose 2	0	1	0	1
Related Loss of appetite Dose 2	8	5	8	21
Any Fever (Axillary) Dose 2	14	12	10	36
Grade 3 Fever (Axillary) Dose 2	2	3	1	6
Related Fever (Axillary) Dose 2	14	12	10	36

Any Diarrhoea/vomiting Dose 3	10	3	3	16
Grade 3 Diarrhoea/vomiting Dose 3	1	0	0	1
Related Diarrhoea/vomiting Dose 3	9	2	1	12
Any Drowsiness Dose 3	16	6	10	32
Grade 3 Drowsiness Dose 3	2	0	1	3
Related Drowsiness Dose 3	16	6	7	29
Any Irritability/fussiness Dose 3	28	15	11	54
Grade 3 Irritability/fussiness Dose 3	7	0	2	9
Related Irritability/fussiness Dose 3	26	15	10	51
Any Loss of appetite Dose 3	16	12	9	37
Grade 3 Loss of appetite Dose 3	2	0	2	4
Related Loss of appetite Dose 3	15	12	7	34
Any Fever (Axillary) Dose 3	20	15	19	54
Grade 3 Fever (Axillary) Dose 3	3	5	3	11
Related Fever (Axillary) Dose 3	19	15	18	52
Any Diarrhoea/vomiting Across doses	17	11	7	35
Grade 3 Diarrhoea/vomiting Across doses	1	1	0	2
Related Diarrhoea/vomiting Across doses	14	5	3	22
Any Drowsiness Across doses	22	18	12	52
Grade 3 Drowsiness Across doses	3	1	2	6
Related Drowsiness Across doses	21	17	12	50
Any Irritability/fussiness Across doses	35	23	15	73
Grade 3 Irritability/fussiness Across doses	10	3	2	15
Related Irritability/fussiness Across doses	35	23	14	72
Any Loss of appetite Across doses	22	18	14	54
Grade 3 Loss of appetite Across doses	2	2	2	6
Related Loss of appetite Across doses	19	17	14	50
Any Fever (Axillary) Across doses	29	19	21	69
Grade 3 Fever (Axillary) Across doses	5	8	4	17
Related Fever (Axillary) Across doses	28	19	20	67

Statistical analyses

No statistical analyses for this end point

Secondary: 25. Number of subjects with medically-attended events (MAEs)

End point title	25. Number of subjects with medically-attended events (MAEs)

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. Analysis of intensity and relationship to vaccination of MAEs was not performed.

End point type	Secondary

End point timeframe:

During the entire study period (from Day 0 to Day 364)

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	46	34	33	113
Units: Subjects				
Any MAE(s)	29	19	20	68

Statistical analyses

No statistical analyses for this end point

Secondary: 26. Number of subjects with potential immune-mediated disease (pIMDs)

End point title	26. Number of subjects with potential immune-mediated disease (pIMDs)

End point description:

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.

End point type	Secondary

End point timeframe:

During the entire study period (from day 0 to Day 364)

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	46	34	33	113
Units: Subjects				
Any pIMDs	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: 27. Number of subjects with unsolicited adverse events (AEs)

End point title	27. Number of subjects with unsolicited adverse events (AEs)

End point description:

An AE is 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. "Any" was defined as an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination. "Grade 3" was defined as an AE which prevented normal, everyday activities. "Related" was defined as

an AE assessed by the investigator as causally related to the study vaccination.

End point type	Secondary

End point timeframe:

During a 21 day follow-up period after each vaccination (Day 0 - Day 21, Day 21 - Day 42, Day 182 - Day 203)

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	46	34	33	113
Units: Subjects				
Any AE(s)	29	19	24	72
Grade 3 AE(s)	5	3	2	10
Related AE(s)	13	5	7	25

Statistical analyses

No statistical analyses for this end point

Secondary: 28. Number of subjects with unsolicited adverse events (AEs)

End point title	28. Number of subjects with unsolicited adverse events (AEs)

End point description:

An AE is 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. "Any" was defined as an incidence of an unsolicited AE regardless of intensity or relationship to study vaccination. "Grade 3" was defined as an AE which prevented normal, everyday activities. "Related" was defined as an AE assessed by the investigator as causally related to the study vaccination.

End point type	Secondary

End point timeframe:

During a Day 84 follow-up period after each vaccination (Day 0 - Day 84, Day 21 - Day 105, Day 182 - Day 266)

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	46	34	33	113
Units: Subjects				
Any AE(s)	32	23	22	77
Grade 3 AE(s)	4	4	2	10
Related AE(s)	9	3	6	18

Statistical analyses

No statistical analyses for this end point

Secondary: 29. Number of subjects with serious adverse events (SAEs)

End point title	29. Number of subjects with serious adverse events (SAEs)

End point description:

Serious adverse events (SAEs) assessed included medical occurrences that result in death, are life threatening, require hospitalization or prolongation of hospitalization or result in disability/ incapacity.

End point type	Secondary

End point timeframe:

During the entire study period (from Day 0 to 364)

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	46	34	33	113
Units: Subjects				
SAEs	5	4	0	9

Statistical analyses

No statistical analyses for this end point

Secondary: 11. Number of seroprotected subjects in terms of H5N1 HI antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point title	11. Number of seroprotected subjects in terms of H5N1 HI antibodies against A/turkey/Turkey/1/2005 H5N1 virus strain

End point description:

A seroprotected subject is defined as a subject with a serum H5N1 HI antibody titer ≥1:40. Data for Day 192 are presented under Primary Outcome Measures.

End point type	Secondary

End point timeframe:

Day 0, Day 182 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	27	32	100
Units: Count of Participants				
A/turkey/Turkey/1/2005 H5N1.HA [Day 0]	0	0	1	1
A/turkey/Turkey/1/2005 H5N1.HA [Day 182]	31	21	29	81

A/turkey/Turkey/1/2005 H5N1.HA [Day 364]	41	27	32	100

Statistical analyses

No statistical analyses for this end point

Secondary: 12. Mean Geometric Change in terms of H5N1 HI antibodies against A/Indonesia/05/2005 H5N1 virus strain

End point title	12. Mean Geometric Change in terms of H5N1 HI antibodies against A/Indonesia/05/2005 H5N1 virus strain

End point description:

Mean Geometric Change is defined as the geometric mean of the within-subject ratios of the post-vaccination reciprocal HI titer to the pre-vaccination (Day 0) reciprocal HI titer (i.e. post-vaccination divided by pre-vaccination titer).

End point type	Secondary

End point timeframe:

At Day 42, Day 182, Day 192 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	27	32	100
Units: Subjects				
A/Indonesia/05/2005 H5N1.HA [Day 42]	32	24	29	85
A/Indonesia/05/2005 H5N1.HA [Day 182]	33	21	29	83
A/Indonesia/05/2005 H5N1.HA [Day 192]	33	21	29	83
A/Indonesia/05/2005 H5N1.HA [Day 364]	41	27	32	100

Statistical analyses

No statistical analyses for this end point

Secondary: 13. Mean Geometric Change in terms of H5N1 HI antibodies against A/turkey/Turkey/01/2005 H5N1 virus strain

End point title	13. Mean Geometric Change in terms of H5N1 HI antibodies against A/turkey/Turkey/01/2005 H5N1 virus strain

End point description:

Mean Geometric Change is defined as the geometric mean of the within-subject ratios of the post vaccination reciprocal HI titer to the pre-vaccination (Day 0) reciprocal HI titer (i.e. post-vaccination divided by pre-vaccination titer). Data for Day 192 are presented under Primary Outcome Measures.

End point type	Secondary

End point timeframe:
Day 182 and Day 364

End point values	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group	GSK1562902A Group
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	41	26	32	99
Units: Subjects				
A/turkey/Turkey/1/2005 H5N1.HA [Day 182]	33	21	29	83
A/turkey/Turkey/1/2005 H5N1.HA [Day 364]	41	26	32	99

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events: From Day 0 to Day 364; Solicited local and general symptoms: During the 7-day (Days 0-6) post-vaccination period; Unsolicited adverse events: During the 84-day (Days 0-84) post-vaccination period.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	15.1

Reporting groups

Reporting group title	GSK1562902A 6 to 12 M Group
Reporting group description: -	
Reporting group title	GSK1562902A 12 to 24 M Group
Reporting group description: -	
Reporting group title	GSK1562902A 24 to 36 M Group

Reporting group description: -

Serious adverse events	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 46 (10.87%)	4 / 34 (11.76%)	0 / 33 (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			
Burns second degree			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (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			
Diarrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (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
Respiratory, thoracic and mediastinal disorders			
Asthma			
alternative assessment type: Non-			

systematic			
subjects affected / exposed	2 / 46 (4.35%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wheezing			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (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			
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 46 (2.17%)	2 / 34 (5.88%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchiolitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 46 (2.17%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (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
Gastroenteritis			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (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
Gastroenteritis rotavirus			
alternative assessment type: Non-systematic			

subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (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
Gastroenteritis viral			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (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
Lobar pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (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
Pneumonia			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (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
Metabolism and nutrition disorders			
Dehydration			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 46 (0.00%)	2 / 34 (5.88%)	0 / 33 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	GSK1562902A 6 to 12 M Group	GSK1562902A 12 to 24 M Group	GSK1562902A 24 to 36 M Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	45 / 46 (97.83%)	32 / 34 (94.12%)	33 / 33 (100.00%)
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0

General disorders and administration site conditions			
Pain			
subjects affected / exposed	27 / 46 (58.70%)	19 / 34 (55.88%)	21 / 33 (63.64%)
occurrences (all)	45	33	45
Swelling			
subjects affected / exposed	6 / 46 (13.04%)	6 / 34 (17.65%)	1 / 33 (3.03%)
occurrences (all)	8	8	2
Pyrexia			
alternative assessment type: Non-systematic			
subjects affected / exposed	31 / 46 (67.39%)	20 / 34 (58.82%)	22 / 33 (66.67%)
occurrences (all)	45	39	40
Chest discomfort			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Injection site haematoma			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Injection site induration			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Injection site rash			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Injection site scab			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 46 (19.57%)	8 / 34 (23.53%)	2 / 33 (6.06%)
occurrences (all)	13	8	6
Rhinorrhoea			
alternative assessment type: Non-systematic			
subjects affected / exposed	11 / 46 (23.91%)	2 / 34 (5.88%)	3 / 33 (9.09%)
occurrences (all)	12	2	4

Asthma			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Choking sensation			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Increased upper airway secretion			
subjects affected / exposed	1 / 46 (2.17%)	2 / 34 (5.88%)	1 / 33 (3.03%)
occurrences (all)	1	2	2
Pharyngeal inflammation			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	0 / 46 (0.00%)	2 / 34 (5.88%)	0 / 33 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Irritability			
subjects affected / exposed	35 / 46 (76.09%)	23 / 34 (67.65%)	15 / 33 (45.45%)
occurrences (all)	63	46	30
Investigations			
Body temperature increased			
subjects affected / exposed	1 / 46 (2.17%)	2 / 34 (5.88%)	0 / 33 (0.00%)
occurrences (all)	1	2	0
Injury, poisoning and procedural complications			
Arthropod bite			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Contusion			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	1 / 33 (3.03%)
occurrences (all)	0	1	1

Foreign body			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Ligament sprain			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Tooth fracture			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Upper limb fracture			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	22 / 46 (47.83%)	18 / 34 (52.94%)	12 / 33 (36.36%)
occurrences (all)	34	27	22
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Eye disorders			
Chalazion			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Conjunctivitis			
subjects affected / exposed	2 / 46 (4.35%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	2	0	2
Eye pain			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	1 / 46 (2.17%)	1 / 34 (2.94%)	2 / 33 (6.06%)
occurrences (all)	1	1	2

Vomiting			
alternative assessment type: Non-systematic			
subjects affected / exposed	17 / 46 (36.96%)	11 / 34 (32.35%)	10 / 33 (30.30%)
occurrences (all)	30	15	12
Teething			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 46 (10.87%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	7	1	0
Abdominal pain			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
alternative assessment type: Non-systematic			
subjects affected / exposed	0 / 46 (0.00%)	3 / 34 (8.82%)	0 / 33 (0.00%)
occurrences (all)	0	3	0
Eczema			
alternative assessment type: Non-systematic			
subjects affected / exposed	1 / 46 (2.17%)	3 / 34 (8.82%)	0 / 33 (0.00%)
occurrences (all)	1	3	0
Blister			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	13 / 46 (28.26%)	6 / 34 (17.65%)	3 / 33 (9.09%)
occurrences (all)	16	7	5
Pruritus			

subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	3 / 46 (6.52%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	3	0	1
Rash macular			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Swelling face			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 46 (0.00%)	0 / 34 (0.00%)	3 / 33 (9.09%)
occurrences (all)	0	0	3
Infections and infestations			
Upper respiratory tract infection			
alternative assessment type: Non-systematic			
subjects affected / exposed	9 / 46 (19.57%)	5 / 34 (14.71%)	12 / 33 (36.36%)
occurrences (all)	11	6	14
Nasopharyngitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	3 / 46 (6.52%)	5 / 34 (14.71%)	2 / 33 (6.06%)
occurrences (all)	3	8	2
Rhinitis			
alternative assessment type: Non-systematic			
subjects affected / exposed	5 / 46 (10.87%)	1 / 34 (2.94%)	2 / 33 (6.06%)
occurrences (all)	6	1	2
Bronchiolitis			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Candidiasis			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Croup infectious			

subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Hand-foot-and-mouth disease			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Otitis media			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	1 / 33 (3.03%)
occurrences (all)	0	1	2
Roseola			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	0 / 33 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	0 / 33 (0.00%)
occurrences (all)	0	1	0
Tonsillitis			
subjects affected / exposed	0 / 46 (0.00%)	1 / 34 (2.94%)	2 / 33 (6.06%)
occurrences (all)	0	1	2
Varicella			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Viral rash			
subjects affected / exposed	1 / 46 (2.17%)	0 / 34 (0.00%)	1 / 33 (3.03%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	22 / 46 (47.83%)	18 / 34 (52.94%)	14 / 33 (42.42%)
occurrences (all)	33	30	24

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 January 2011	Amendment 1 The former version of the protocol was published in two versions, due to a tehnical problem. The first version contained errors in the tables of intensity. This version was submitted in Singapore. The second version contained errors in the vaccine tables, where commas where left out in the volumes. This version was submitted in Australia. This Amendment is based on the latter version of the final protocol. Therefore, track changes will not be found in the amendment, although a difference exists with the version submitted in Singapore. The changes have been brought to the tables as explained under Section 8.2.2.2.1. Additional changes have been brought to clarify the contents of the vials and vaccine doses.
16 June 2011	Amendment 2 The protocol was amended to exclude subjects who had a past medical history of infection with a H5N1 virus or vaccination with a H5N1 vaccine. Exclusion criteria were updated accordingly. In addition, procedures for collection of medically-attended adverse events between Day 203 and Day 364 have been clarified.
04 November 2011	Amendment 3 With Amendment 3, the protocol was adjusted to document that the age stratification ratio of 2:1:1 for children 6 to 11 months, 12 to 23 months, and 24 to 35 months of age, respectively, was not be maintained due to recruitment difficulties. The overall subjects enrolment goal were not change.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported