Clinical trial results:
Consistency, Immunogenicity and Safety Study of GlaxoSmithKline (GSK) Biologicals' Herpes Zoster (HZ) Vaccine GSK1437173A in Adults 50 Years of Age

Summary

EudraCT number	2013-000373-76
Trial protocol	BE
Global end of trial date	25 April 2016

Results information

Result version number	v1
This version publication date	07 January 2017
First version publication date	07 January 2017

Trial information

Trial identification

Sponsor protocol code	117177

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02075515
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 October 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To demonstrate lot-to-lot consistency in terms of anti-gE humoral immunogenicity between three production lots of the HZ/su vaccine one month after the second dose (Month 3).
One month after the second dose, the two-sided 95 % confidence intervals (CI) of the geometric mean concentration (GMC) ratio between all pairs of lots were within [0.67, 1.5].

Protection of trial subjects:

All subjects were supervised for 30 min after vaccination/product administration with appropriate medical treatment readily available. Any subject with an event of HZ between Visit 1 and Visit 2 did not receive the second dose.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 August 2014
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	Belgium: 276
Country: Number of subjects enrolled	Canada: 93
Country: Number of subjects enrolled	United States: 282
Worldwide total number of subjects	651
EEA total number of subjects	276

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	0

From 65 to 84 years	651
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

At screening the following was performed: informed consent was obtained from & signed by subjects' parents/gardians, check for inclusion/exclusion criteria and precautions was performed as regards contraindications to vaccination, and medical history of subjects was collected. Subjects' pre-vaccination body temperature was evaluated.

Pre-assignment period milestones

Number of subjects started	651
Number of subjects completed	651

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	GSK1437173A Lot A Group

Arm description:

Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot A, administered intramuscularly in the deltoid region of non-dominant arm, at 0 and 2 months.

Arm type	Experimental
Investigational medicinal product name	Herpes zoster vaccine GSK1437173A
Investigational medicinal product code	HZ/su or gE/AS01B
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a dose from Lot A, B or C of the GSK1437173A vaccine at 0 and 2 months.

Arm title	GSK1437173A Lot B Group

Arm description:

Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot B, administered intramuscularly in deltoid region of non-dominant arm, at 0 and 2 months.

Arm type	Experimental
Investigational medicinal product name	Herpes zoster vaccine GSK1437173A
Investigational medicinal product code	HZ/su or gE/AS01B
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a dose from Lot A, B or C of the GSK1437173A vaccine at 0 and 2 months.

Arm title	GSK1437173A Lot C Group

Arm description:

Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot C, administered intramuscularly in deltoid region of non-dominant arm, at 0 and 2 months.

Arm type	Experimental
Investigational medicinal product name	Herpes zoster vaccine GSK1437173A
Investigational medicinal product code	HZ/su or gE/AS01B
Other name	
Pharmaceutical forms	Powder and solvent for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

Subjects received a dose from Lot A, B or C of the GSK1437173A vaccine at 0 and 2 months.

Number of subjects in period 1	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group
Started	218	217	216
Completed	214	212	208
Not completed	4	5	8
Consent withdrawn by subject	2	-	1
Non-Serious Adverse Event	-	1	-
Lost to follow-up	1	3	6
Serious Adverse Event	1	1	1

Baseline characteristics

Reporting groups	
Reporting group title	GSK1437173A Lot A Group
Reporting group description:	
Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot A, administered intramuscularly in the deltoid region of non-dominant arm, at 0 and 2 months.	
Reporting group title	GSK1437173A Lot B Group
Reporting group description:	
Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot B, administered intramuscularly in deltoid region of non-dominant arm, at 0 and 2 months.	
Reporting group title	GSK1437173A Lot C Group
Reporting group description:	
Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot C, administered intramuscularly in deltoid region of non-dominant arm, at 0 and 2 months.	

Reporting group values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group
Number of subjects	218	217	216
Age categorical Units: Subjects			
Age continuous			
Age continuous description			
Units: years arithmetic mean standard deviation	 64.8 ± 8.8	 64.3 ± 9.4	 64.4 ± 8.8
Gender categorical			
Gender categorical description			
Units: Subjects			
Female	116	130	114
Male	102	87	102

Reporting group values	Total		
Number of subjects	651		
Age categorical Units: Subjects			
Age continuous			
Age continuous description			
Units: years arithmetic mean standard deviation	 -		
Gender categorical			
Gender categorical description			

Units: Subjects			
Female	360		
Male	291		

End points

End points reporting groups

Reporting group title	GSK1437173A Lot A Group
Reporting group description:	
Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot A, administered intramuscularly in the deltoid region of non-dominant arm, at 0 and 2 months.	
Reporting group title	GSK1437173A Lot B Group
Reporting group description:	
Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot B, administered intramuscularly in deltoid region of non-dominant arm, at 0 and 2 months.	
Reporting group title	GSK1437173A Lot C Group
Reporting group description:	
Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot C, administered intramuscularly in deltoid region of non-dominant arm, at 0 and 2 months.	

Primary: Number of subjects with anti-gE antibody concentrations equal to or above the cut-off value

End point title	Number of subjects with anti-gE antibody concentrations equal to or above the cut-off value
End point description:	
Anti-gE antibody concentrations, as determined by Enzyme-linked Immunosorbent Assay (ELISA). The cut-off value was ≥ 97 milli international units per milliliter (mIU/mL).	
End point type	Primary
End point timeframe:	
At Month 3	

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	210	202	
Units: Subjects	210	210	202	

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	GSK1437173A Lot B Group v GSK1437173A Lot A Group

Number of subjects included in analysis	420
Analysis specification	Pre-specified
Analysis type	
Method	ANCOVA
Parameter estimate	Adjusted GMC Ratio
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.86
upper limit	1.09

Statistical analysis title	Statistical analysis 2
Comparison groups	GSK1437173A Lot C Group v GSK1437173A Lot A Group
Number of subjects included in analysis	412
Analysis specification	Pre-specified
Analysis type	
Method	ANCOVA
Parameter estimate	Adjustd GMC Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.08

Statistical analysis title	Statistical analysis 3
Comparison groups	GSK1437173A Lot B Group v GSK1437173A Lot C Group
Number of subjects included in analysis	412
Analysis specification	Pre-specified
Analysis type	
Method	ANCOVA
Parameter estimate	Adjusted GMC ratio
Point estimate	0.99
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	1.1

Secondary: Anti-gE humoral immunogenicity	
End point title	Anti-gE humoral immunogenicity

End point description:

Anti-gE antibody concentrations, were determined by ELISA, expressed as Geometric Mean

Concentrations (GMCs), in milli international units per milliliter (mIU/mL).

End point type	Secondary

End point timeframe:

At Month 0 and Month 3

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	210	202	
Units: mIU/mL				
geometric mean (confidence interval 95%)				
Anti-gE, Month 0	1378.4 (1180 to 1610)	1166.5 (1005.5 to 1353.4)	1381.2 (1190.9 to 1601.9)	
Anti-gE, Month 3	59556.1 (54587.6 to 64976.7)	60733.8 (55995.2 to 65873.3)	62058.3 (57422.3 to 67068.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of vaccine responders for anti-gE concentrations as determined by ELISA

End point title	Number of vaccine responders for anti-gE concentrations as determined by ELISA

End point description:

Vaccine response was defined as: For initially seronegative subjects, antibody concentration at post-vaccination ≥ 4 fold the cut-off for Anti-gE (4x97 mIU/mL); For initially seropositive subjects, antibody concentration at post-vaccination ≥ 4 fold the pre-vaccination antibody concentration.

End point type	Secondary

End point timeframe:

At Month 3

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	210	210	202	
Units: Subjects	201	205	197	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Assessed solicited local symptoms were pain, redness and swelling. Any = occurrence of the symptom regardless of intensity grade. Grade 3 pain = significant pain at rest, that prevented normal every day activities.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after each vaccine dose and across doses

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	217	217	215	
Units: Subjects				
Any Pain, Dose 1 (N=217;217;214)	160	179	166	
Grade 3 Pain, Dose 1 (N=217;217;214)	4	6	7	
Any Redness, Dose 1 (N=217;217;214)	29	48	41	
Grade 3 Redness, Dose 1 (N=217;217;214)	1	1	1	
Any Swelling, Dose 1 (N=217;217;214)	24	33	26	
Grade 3 Swelling, Dose 1 (N=217;217;214)	0	0	1	
Any Pain, Dose 2 (N=211;216;207)	155	152	155	
Grade 3 Pain, Dose 2 (N=211;216;207)	18	13	7	
Any Redness, Dose 2 (N=211;216;207)	38	47	43	
Grade 3 Redness, Dose 2 (N=211;216;207)	3	2	2	
Any Swelling, Dose 2 (N=211;216;207)	22	28	25	
Grade 3 Swelling, Dose 2 (N=211;216;207)	3	1	1	
Any Pain, Across Doses (N=217;217;215)	188	196	185	
Grade 3 Pain, Across Doses (N=217;217;215)	22	16	13	
Any Redness, Across Doses (N=217;217;215)	52	68	62	
Grade 3 Redness, Across Doses (N=217;217;215)	4	3	3	
Any Swelling, Across Doses (N=217;217;215)	38	44	39	
Grade 3 Swelling, Across Doses (N=217;217;215)	3	1	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of days with any solicited local symptoms

End point title	Number of days with any solicited local symptoms

End point description:

The number of days with any local symptoms reported during the solicited post-vaccination period.

End point type	Secondary

End point timeframe:

During the 7 days (Days 0-6) after each vaccine dose and overall

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	218	217	216	
Units: Days				
median (inter-quartile range (Q1-Q3))				
Pain post-Dose 1	2 (2 to 3.5)	3 (2 to 3)	3 (2 to 4)	
Pain post-Dose 2	2 (2 to 4)	2 (2 to 3)	2 (2 to 3)	
Redness post-Dose 1	2 (2 to 3)	3 (1.5 to 3)	2 (2 to 4)	
Redness post-Dose 2	3 (2 to 4)	3 (2 to 3)	3 (2 to 3)	
Swelling post-Dose 1	2 (1 to 3)	2 (1 to 3)	3 (2 to 4)	
Swelling post-Dose 2	3 (2 to 4)	3 (2 to 4)	3 (2 to 3)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Assessed solicited general symptoms were fatigue, gastrointestinal (nausea, vomiting, diarrhea and/or abdominal pain), headache, myalgia, shivering and temperature [defined as oral temperature equal to or above 37.5 degrees Celsius (°C)]. Any = occurrence of the symptom regardless of intensity grade. Grade 3 symptom = symptom that prevented normal activity. Grade 3 temperature= temperature > 39.0 °C. Related = symptom assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

Within 7 days (Days 0-6) after each vaccine dose and across doses

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	217	217	216	
Units: Subjects				
Any Fatigue, Dose 1 (N=217;217;215)	66	68	64	
Grade 3 Fatigue, Dose 1 (N=217;217;215)	5	4	4	

Related Fatigue, Dose 1 (N=217;217;215)	62	63	58	
Any Gastrointestinal, Dose 1 (N=217;217;215)	23	22	26	
Grade 3 Gastrointestinal, Dose 1 (N=217;217;215)	1	0	4	
Related Gastrointestinal, Dose 1 (N=217;217;215)	19	20	23	
Any Headache, Dose 1 (N=217;217;215)	63	68	49	
Grade 3 Headache, Dose 1 (N=217;217;215)	5	4	4	
Related Headache, Dose 1 (N=217;217;215)	59	63	43	
Any Myalgia, Dose 1 (N=217;217;215)	85	89	76	
Grade 3 Myalgia, Dose 1 (N=217;217;215)	4	3	4	
Related Myalgia, Dose 1 (N=217;217;215)	71	78	62	
Any Shivering, Dose 1 (N=217;217;215)	31	21	22	
Grade 3 Shivering, Dose 1 (N=217;217;215)	1	4	0	
Related Shivering, Dose 1 (N=217;217;215)	30	19	21	
Any Temperature, Dose 1 (N=217;217;215)	28	23	22	
Grade 3 Temperature, Dose 1 (N=217;217;215)	0	0	0	
Related Temperature, Dose 1 (N=217;217;215)	24	21	19	
Any Fatigue, Dose 2 (N=212;216;208)	91	85	82	
Grade 3 Fatigue, Dose 2 (N=212;216;208)	14	7	6	
Related Fatigue, Dose 2 (N=212;216;208)	89	80	76	
Any Gastrointestinal, Dose 2 (N=212;216;208)	33	34	29	
Grade 3 Gastrointestinal, Dose 2 (N=212;216;208)	2	2	5	
Related Gastrointestinal, Dose 2 (N=212;216;208)	29	29	28	
Any Headache, Dose 2 (N=212;216;208)	74	80	66	
Grade 3 Headache, Dose 2 (N=212;216;208)	9	11	5	
Related Headache, Dose 2 (N=212;216;208)	69	76	63	
Any Myalgia, Dose 2 (N=212;216;208)	99	91	83	
Grade 3 Myalgia, Dose 2 (N=212;216;208)	20	11	7	
Related Myalgia, Dose 2 (N=212;216;208)	85	81	76	
Any Shivering, Dose 2 (N=212;216;208)	67	60	44	
Grade 3 Shivering, Dose 2 (N=212;216;208)	11	5	7	
Related Shivering, Dose 2 (N=212;216;208)	66	59	43	
Any Temperature, Dose 2 (N=212;216;208)	43	34	25	

Grade 3 Temperature, Dose 2 (N=212;216;208)	2	0	1	
Related Temperature, Dose 2 (N=212;216;208)	40	33	25	
Any Fatigue, Across Doses (N=217;217;216)	114	109	107	
Grade 3 Fatigue, Across Doses (N=217;217;216)	18	11	10	
Related Fatigue, Across Doses (N=217;217;216)	111	102	103	
Any Gastrointestinal, Across Doses (N=217;217;216)	46	45	50	
Grade3 Gastrointestinal,Across Doses(N=217;217;216	3	2	9	
Any Headache, Across Doses (N=217;217;216)	101	108	89	
Grade 3 Headache, Across Doses (N=217;217;216)	13	13	9	
Related Headache, Across Doses (N=217;217;216)	95	101	82	
Any Myalgia, Across Doses (N=217;217;216)	128	119	113	
Grade 3 Myalgia, Across Doses (N=217;217;216)	24	12	10	
Related Myalgia, Across Doses (N=217;217;216)	112	107	102	
Any Shivering, Across Doses (N=217;217;216)	80	67	60	
Grade 3 Shivering, Across Doses (N=217;217;216)	12	7	7	
Related Shivering, Across Doses (N=217;217;216)	79	65	58	
Any Temperature, Across Doses (N=217;217;216)	59	49	43	
Grade 3 Temperature, Across Doses (N=217;217;216)	2	0	1	
Related Temperature, Across Doses (N=217;217;216)	53	46	41	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of days with any solicited general symptoms

End point title	Number of days with any solicited general symptoms

End point description:

The number of days with any general symptoms reported during the solicited post-vaccination period.

End point type	Secondary

End point timeframe:

During the 7 days (Days 0-6) after each vaccine dose and overall

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	218	217	216	
Units: Days				
median (inter-quartile range (Q1-Q3))				
Fatigue post-Dose 1	2 (1 to 2)	2 (1 to 3)	2 (1 to 3)	
Fatigue post-Dose 2	2 (1 to 2)	2 (1 to 3)	1.5 (1 to 2)	
Gastrointestinal symptoms post-Dose 1	1 (1 to 2)	1 (1 to 2)	1 (1 to 2)	
Gastrointestinal symptoms post-Dose 2	1 (1 to 2)	1 (1 to 2)	1 (1 to 2)	
Headache post-Dose 1	1 (1 to 2)	1.5 (1 to 2)	2 (1 to 3)	
Headache post-Dose 2	1 (1 to 2)	1 (1 to 2)	2 (1 to 3)	
Myalgia post-Dose 1	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	
Myalgia post-Dose 2	2 (1 to 3)	2 (1 to 3)	2 (1 to 3)	
Shivering post-Dose 1	1 (1 to 2)	2 (1 to 2)	1 (1 to 2)	
Shivering post-Dose 2	1 (1 to 2)	1 (1 to 1.5)	1 (1 to 2)	
Temperature post-Dose 1	1 (1 to 1)	1 (1 to 2)	1 (1 to 1)	
Temperature post-Dose 2	1 (1 to 1)	1 (1 to 1)	1 (1 to 2)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any potential Immune-Mediated Diseases (pIMDs)

End point title	Number of subjects with any potential Immune-Mediated Diseases (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:

From first vaccination up to 30 days post last vaccination (Month 0-Month 3) and from Month 4 until study end (Month 14)

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	218	217	216	
Units: Subjects				
pIMDs from Month 0 to Month 3	3	0	1	
pIMDs from Month 4 to Month 14	2	0	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any, Grade 3 and related unsolicited adverse events (AEs)

End point title	Number of subjects with any, Grade 3 and related unsolicited adverse events (AEs)

End point description:

An unsolicited AE covers any untoward medical occurrence in a clinical investigation subject temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product and reported in addition to those solicited during the clinical study and any solicited symptom with onset outside the specified period of follow-up for solicited symptoms. Any was defined as the occurrence of any unsolicited AE regardless of intensity grade or relation to vaccination. Grade 3 AE = an AE which prevented normal, everyday activities. Related = AE assessed by the investigator as related to the vaccination.

End point type	Secondary

End point timeframe:

During 30 days (Days 0-29) after each vaccination

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	218	217	216	
Units: Subjects				
Any AE(s)	72	69	76	
Grade 3 AE(s)	13	15	9	
Related AE(s)	23	22	27	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of subjects with any Serious Adverse Events (SAEs)

End point title	Number of subjects with any Serious Adverse Events (SAEs)

End point description:

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

End point type	Secondary

End point timeframe:

From first vaccination up to 30 days post last vaccination (Month 0-Month 3) and from Month 4 to study end (Month 14)

End point values	GSK1437173A Lot A Group	GSK1437173A Lot B Group	GSK1437173A Lot C Group	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	218	217	216	
Units: Subjects				
SAEs from Month 0 to Month 3	5	7	4	
SAEs from Month 4 to Month 14	10	8	16	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Solicited local and general symptoms: within 7 days (Days 0-6) after each vaccination; Unsolicited AEs: during 30 days (Days 0-29) after each vaccination; SAEs: from first vaccination up to study end (Month 0-Month 14).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	GSK1437173A Lot A Group

Reporting group description:

Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot A, administered intramuscularly in the deltoid region of non-dominant arm, at 0 and 2 months.

Reporting group title	GSK1437173A Lot C Group

Reporting group description:

Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot C, administered intramuscularly in deltoid region of non-dominant arm, at 0 and 2 months.

Reporting group title	GSK1437173A Lot B Group

Reporting group description:

Male and female subjects, aged ≥ 50 years at the time of study vaccination, received a dose of the GSK1437173A vaccine from Lot B, administered intramuscularly in deltoid region of non-dominant arm, at 0 and 2 months.

Serious adverse events	GSK1437173A Lot A Group	GSK1437173A Lot C Group	GSK1437173A Lot B Group
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 218 (5.96%)	20 / 216 (9.26%)	14 / 217 (6.45%)
number of deaths (all causes)	1	1	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bladder cancer			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Breast cancer			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon cancer			

subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningioma			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Renal cell carcinoma			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Squamous cell carcinoma of lung			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 218 (0.46%)	1 / 216 (0.46%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Chronic obstructive pulmonary disease			

subjects affected / exposed	1 / 218 (0.46%)	1 / 216 (0.46%)	0 / 217 (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
Pulmonary embolism			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	2 / 217 (0.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary hypertension			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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 arrest			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Psychiatric disorders			
Schizophrenia			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Injury, poisoning and procedural complications			
Animal bite			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Humerus fracture			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Limb injury			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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

Subdural haematoma			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Vascular pseudoaneurysm			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	1 / 218 (0.46%)	1 / 216 (0.46%)	0 / 217 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Atrial flutter			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Cardiac failure congestive			
subjects affected / exposed	2 / 218 (0.92%)	2 / 216 (0.93%)	0 / 217 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mitral valve incompetence			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Myocardial infarction			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Sinus node dysfunction			

subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Supraventricular tachycardia			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Migraine			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuromyelitis optica spectrum disorder			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Parkinson’s disease			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Presyncope			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Radiculopathy			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Spinal claudication			

subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Syncope			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Blood and lymphatic system disorders			
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Pancreatitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pancreatitis necrotising			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	2 / 218 (0.92%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post cholecystectomy syndrome			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Haematuria			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Hydronephrosis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary incontinence			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	2 / 217 (0.92%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Muscle spasms			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteoarthritis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Spinal column stenosis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Vertebral foraminal stenosis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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

Vertebral osteophyte			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	0 / 217 (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
Cellulitis			
subjects affected / exposed	1 / 218 (0.46%)	1 / 216 (0.46%)	0 / 217 (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
Infective exacerbation of chronic obstructive airways			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreas infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parainfluenzae virus infection			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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
Pyelonephritis			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Sepsis			
subjects affected / exposed	0 / 218 (0.00%)	1 / 216 (0.46%)	2 / 217 (0.92%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 218 (0.46%)	0 / 216 (0.00%)	0 / 217 (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			
Malnutrition			
subjects affected / exposed	0 / 218 (0.00%)	0 / 216 (0.00%)	1 / 217 (0.46%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
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	GSK1437173A Lot A Group	GSK1437173A Lot C Group	GSK1437173A Lot B Group
Total subjects affected by non-serious adverse events			
subjects affected / exposed	202 / 218 (92.66%)	198 / 216 (91.67%)	201 / 217 (92.63%)
Nervous system disorders			
Headache			
subjects affected / exposed	101 / 218 (46.33%)	89 / 216 (41.20%)	108 / 217 (49.77%)
occurrences (all)	141	115	152
General disorders and administration site conditions			
Chills			
subjects affected / exposed	80 / 218 (36.70%)	61 / 216 (28.24%)	67 / 217 (30.88%)
occurrences (all)	99	67	81
Fatigue			
subjects affected / exposed	114 / 218 (52.29%)	107 / 216 (49.54%)	109 / 217 (50.23%)
occurrences (all)	157	147	153
Pain			

subjects affected / exposed	188 / 218 (86.24%)	185 / 216 (85.65%)	196 / 217 (90.32%)
occurrences (all)	315	321	331
Pyrexia			
subjects affected / exposed	60 / 218 (27.52%)	43 / 216 (19.91%)	50 / 217 (23.04%)
occurrences (all)	72	48	58
Swelling			
subjects affected / exposed	38 / 218 (17.43%)	40 / 216 (18.52%)	44 / 217 (20.28%)
occurrences (all)	46	52	61
Gastrointestinal disorders			
Gastrointestinal disorder			
subjects affected / exposed	46 / 218 (21.10%)	50 / 216 (23.15%)	45 / 217 (20.74%)
occurrences (all)	56	55	56
Skin and subcutaneous tissue disorders			
Erythema			
subjects affected / exposed	55 / 218 (25.23%)	62 / 216 (28.70%)	70 / 217 (32.26%)
occurrences (all)	70	84	98
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	128 / 218 (58.72%)	113 / 216 (52.31%)	119 / 217 (54.84%)
occurrences (all)	184	160	181
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	7 / 218 (3.21%)	11 / 216 (5.09%)	7 / 217 (3.23%)
occurrences (all)	7	11	7

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 April 2014	• At CBER's request, the three production lots of the HZ/su vaccines will be randomly assigned unique combinations of three "consecutive" adjuvant lots DA01A056A, DA01A058A and DA01A059B with the three consecutive gE lots: DVZVA009, DVZVA010 and DVZVA011. • The descriptive secondary objective evaluating the consistency of the three vaccines lots in terms of vaccine response has been changed to a confirmatory objective with a criterion. Statistical methods for power calculation for this secondary objective has been added. • As a consequence, the number of subjects foreseen in the study has been increased from 150 subjects per group to 217 subjects per group: This increased sample size will give 195 evaluable subjects in each vaccine lot group to have at least 99% probability to reach the primary objective. Sample size and power calculation for the primary objective has been updated to this end. • List of potential immune-mediated diseases has been updated. • To control the type I error, a hierarchical procedure will be used for the primary and secondary (immunogenicity) objectives. Each objective can only be reached if all the associated criteria are met and all previous objectives have been reached.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported