



## Clinical trial results:

**A Phase III, randomised, observer-blind, placebo-controlled, multicentre clinical study to assess the immunogenicity and safety of GSK Biologicals? HZ/su candidate vaccine when administered intramuscularly on a 0- and 1- to 2-months schedule to adults > 18 years of age with renal transplant.**

### Summary

EudraCT number	2012-005059-18
Trial protocol	ES CZ BE FI IT
Global end of trial date	

### Results information

Result version number	v1
This version publication date	27 May 2017
First version publication date	27 May 2017

### Trial information

#### Trial identification

Sponsor protocol code	116886
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#### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02058589
WHO universal trial number (UTN)	-

Notes:

### Sponsors

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

Notes:

### Paediatric regulatory details

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

Notes:

## Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	08 December 2016
Is this the analysis of the primary completion data?	Yes
Primary completion date	11 May 2016
Global end of trial reached?	No

Notes:

## General information about the trial

Main objective of the trial:

- To evaluate vaccine response rate (VRR) for anti-glycoprotein E (anti-gE) humoral immune responses at Month 2, following a two-dose administration of the HZ/su vaccine, in all subjects.

Criterion to be used:

The objective was met if the lower limit of the 95% confidence interval (CI) of the VRR for anti-gE antibody (Ab) concentrations at Month 2 in the HZ/su vaccine group was at least 60%.

- To evaluate the safety following administration of HZ/su vaccine, as compared to placebo, from the first vaccination up to 30 days post last vaccination in all subjects.

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	20 March 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	Canada: 26
Country: Number of subjects enrolled	Czech Republic: 25
Country: Number of subjects enrolled	Finland: 10
Country: Number of subjects enrolled	Belgium: 17
Country: Number of subjects enrolled	Italy: 7
Country: Number of subjects enrolled	Korea, Republic of: 39
Country: Number of subjects enrolled	Panama: 8
Country: Number of subjects enrolled	Spain: 119
Country: Number of subjects enrolled	Taiwan: 14
Worldwide total number of subjects	265
EEA total number of subjects	178

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)	265
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details: -

### Pre-assignment period milestones

Number of subjects started	265
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Number of subjects completed	264
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### Pre-assignment subject non-completion reasons

Reason: Number of subjects	Study vaccine not received: 1
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### Period 1

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

As long as the study is still ongoing, information for the study arms remains blindd and will be presented in a pooled manner.

### Arms

Arm title	Overall Study Group
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Arm description:

Subjects, aged 18 years or older, received 2 doses of the GSK 1437173A vaccine or placebo at Day 0, and Month 1.

Arm type	Experimental
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Investigational medicinal product name	Placebo
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Investigational medicinal product code	
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Other name	lyophilised sucrose reconstituted with saline [NaCl] solution
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Pharmaceutical forms	Powder and solution for solution for injection
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Routes of administration	Intramuscular use
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Dosage and administration details:

2 doses at Day 0, and Month 1

Investigational medicinal product name	Herpes Zoster vaccine GSK1437173A
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Investigational medicinal product code	
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Other name	
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Pharmaceutical forms	Powder and solvent for suspension for injection
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Routes of administration	Intramuscular use
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Dosage and administration details:

2 doses at Day 0, and Month 1

<b>Number of subjects in period 1<sup>[1]</sup></b>	Overall Study Group
Started	264
Completed	261
Not completed	3
Adverse event, non-fatal	3

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Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: 1 enrolled subject did not receive vaccination and hence did not start the study.

## Baseline characteristics

### Reporting groups

Reporting group title	Overall Study Group
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Reporting group description:

Subjects, aged 18 years or older, received 2 doses of the GSK 1437173A vaccine or placebo at Day 0, and Month 1.

Reporting group values	Overall Study Group	Total	
Number of subjects	264	264	
Age categorical			
Units: Subjects			

Age continuous			
Units: years			
geometric mean	52.4		
standard deviation	± 12.6	-	
Gender categorical			
Units: Subjects			
Female	79	79	
Male	185	185	
Race/Ethnicity, Customized			
Units: Subjects			
African Heritage / African American	4	4	
Asian - Central/South Asian Heritage	3	3	
Asian - East Asian Heritage	42	42	
Asian - Japanese Heritage	1	1	
Asian - South East Asian Heritage	13	13	
White - Arabic / North African Heritage	4	4	
White - Caucasian / European Heritage	185	185	
Other	12	12	

## End points

### End points reporting groups

Reporting group title	Overall Study Group
Reporting group description: Subjects, aged 18 years or older, received 2 doses of the GSK 1437173A vaccine or placebo at Day 0, and Month 1.	
Subject analysis set title	GSK1437173A Group
Subject analysis set type	Per protocol
Subject analysis set description: Subjects, aged 18 years or older, received 2 doses of the GSK 1437173A vaccine, adjuvanted with AS01B at Day 0, and Month 1	
Subject analysis set title	Placebo Group
Subject analysis set type	Per protocol
Subject analysis set description: Subjects, aged 18 years or older, received 2 doses of Placebo (lyophilised sucrose reconstituted with saline [NaCl] solution) at Day 0, and Month 1.	

### Primary: Number of subjects with a Vaccine response for anti-gE humoral immunogenicity

End point title	Number of subjects with a Vaccine response for anti-gE humoral immunogenicity <sup>[1]</sup>
End point description: Vaccine response was determined by ELISA	
End point type	Primary
End point timeframe: At Month 2.	
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: There were no statistical analyses needed for this endpoint as it was descriptive.	

End point values	GSK1437173A Group	Placebo Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	119		
Units: Participants				
Participants	97	5		

### Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with any potential immune-mediated diseases (pIMDs)

End point title	Number of subjects with any potential immune-mediated diseases (pIMDs) <sup>[2]</sup>
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	Primary

End point timeframe:

From first vaccination up to 30 days post last vaccination.

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: There were no statistical analyses needed for this endpoint as it was descriptive.

End point values	Overall Study Group			
Subject group type	Reporting group			
Number of subjects analysed	264			
Units: Participants				
Participants	0			

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with any and related serious adverse events (SAEs)

End point title	Number of subjects with any and related serious adverse events (SAEs) <sup>[3]</sup>
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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	Primary
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End point timeframe:

From first vaccination up to 30 days post last vaccination

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: There were no statistical analyses needed for this endpoint as it was descriptive.

End point values	Overall Study Group			
Subject group type	Reporting group			
Number of subjects analysed	264			
Units: Participants				
Participants	11			

## Statistical analyses

No statistical analyses for this end point

### Primary: Number of subjects with biopsy confirmed renal allograft rejection

End point title	Number of subjects with biopsy confirmed renal allograft rejection <sup>[4]</sup>
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End point description:

End point type	Primary
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End point timeframe:

From the first vaccination up to 30 days post last vaccination.

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: There were no statistical analyses needed for this endpoint as it was descriptive.

End point values	Overall Study Group			
Subject group type	Reporting group			
Number of subjects analysed	264			
Units: Participants				
Rejection	0			
No rejection	3			

### Statistical analyses

No statistical analyses for this end point

### Secondary: Number of subjects with a vaccine response for anti-gE antibodies

End point title	Number of subjects with a vaccine response for anti-gE antibodies
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End point description:

Cut-off value for the vaccine response was 97 milli-international units per millilitre (mIU/mL).

End point type	Secondary
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End point timeframe:

At Months 1

End point values	GSK1437173A Group	Placebo Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	119		
Units: Participants				
Participants	77	3		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Anti-gE antibody concentrations

End point title	Anti-gE antibody concentrations
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End point description:

Varicella Zoster Virus.glycoprotein E Ab.Immunoglobulin G was determined by ELISA assay.

End point type	Secondary
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End point timeframe:

At Months 0, 1 and 2

End point values	GSK1437173A Group	Placebo Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	121	119		
Units: mIU/mL				
geometric mean (confidence interval 95%)				
anti-gE, Month 0	1354.4 (1118.3 to 1640.4)	1495.7 (1202.3 to 1860.8)		
anti-gE, Month 1	9530.5 (7111.3 to 12772.7)	1501.9 (1231.3 to 1832)		
anti-gE, Month 2	19163.8 (15041.5 to 24416)	1489.4 (1215.8 to 1824.7)		

### Statistical analyses

No statistical analyses for this end point

### Secondary: Frequencies of gE-specific CD4+ T-cells

End point title	Frequencies of gE-specific CD4+ T-cells
End point description: gE-specific CD4+ T-cells, expressing at least two activation markers (from among interferon gamma [IFN- $\gamma$ ], interleukin-2 [IL-2], tumour necrosis factor alpha [TNF- $\alpha$ ] and CD40L), as determined by in vitro ICS	
End point type	Secondary
End point timeframe: At Months 0 and 2	

End point values	GSK1437173A Group	Placebo Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	31	32		
Units: gE-specific CD4+ T-cells/million T-cells				
arithmetic mean (standard deviation)				
Month 0	110.9 ( $\pm$ 182.09)	165.75 ( $\pm$ 242.92)		
Month 2	165.75 ( $\pm$ 242.92)	156.98 ( $\pm$ 274.81)		

## Statistical analyses

No statistical analyses for this end point

## Secondary: Number of subjects with Vaccine response for gE-specific CD4+ T-cells

End point title	Number of subjects with Vaccine response for gE-specific CD4+ T-cells
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End point description:

Vaccine response for gE-specific CD4+ T-cells expressing at least two activation markers (from among IFN- $\gamma$ , IL-2, TNF- $\alpha$  and CD40L), as determined by in vitro ICS

End point type	Secondary
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End point timeframe:

At Months 2 and 13

<b>End point values</b>	GSK1437173A Group	Placebo Group		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	28	28		
Units: Participants				
Participants	20	0		

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information<sup>[1]</sup>

Timeframe for reporting adverse events:

Solicited local and general: within 7 days (Days 0-6) after each vaccination; AEs: during 30 days (Days 0-29) after each vaccination; SAEs: from the first vaccination up to study end at Month 13

Adverse event reporting additional description:

The frequent adverse events were being re-analyzed and not available at the time of posting. They will be added once validated.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	19.0
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### Reporting groups

Reporting group title	Overall Study Group
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Reporting group description:

Subjects, aged 18 years or older, received 2 doses of the GSK 1437173A vaccine or placebo at Day 0, and Month 1.

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: The frequent adverse events were being re-analyzed and not available at the time of posting. They will be added once validated.

Serious adverse events	Overall Study Group		
Total subjects affected by serious adverse events			
subjects affected / exposed	58 / 264 (21.97%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign gastrointestinal neoplasm			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Breast cancer			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Burkitt's lymphoma			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Squamous cell carcinoma of skin			

subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pregnancy, puerperium and perinatal conditions			
Abortion spontaneous incomplete			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Mucosal inflammation			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Kidney transplant rejection			
subjects affected / exposed	3 / 264 (1.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Transplant rejection			
subjects affected / exposed	5 / 264 (1.89%)		
occurrences causally related to treatment / all	0 / 5		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood creatinine increased			
subjects affected / exposed	3 / 264 (1.14%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			

Contusion			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Multiple fractures			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Radius fracture			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Road traffic accident			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Upper limb fracture			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular graft stenosis			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular graft thrombosis			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Coronary artery disease			

subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Myocardial infarction			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Enteritis			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			

subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal cyst			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal impairment			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Atypical pneumonia			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Beta haemolytic streptococcal infection			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Clostridium colitis			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Erysipelas			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Escherichia infection			



subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	6 / 264 (2.27%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Helicobacter gastritis				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	4 / 264 (1.52%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	3 / 264 (1.14%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Klebsiella sepsis				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Localised infection				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Meningitis				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pneumonia				

subjects affected / exposed	2 / 264 (0.76%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Postoperative wound infection				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis acute				
subjects affected / exposed	5 / 264 (1.89%)			
occurrences causally related to treatment / all	0 / 5			
deaths causally related to treatment / all	0 / 0			
Renal graft infection				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	1 / 264 (0.38%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	5 / 264 (1.89%)			
occurrences causally related to treatment / all	0 / 6			
deaths causally related to treatment / all	0 / 0			
Urosepsis				

subjects affected / exposed	2 / 264 (0.76%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Viral infection			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 264 (0.38%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

<b>Non-serious adverse events</b>	Overall Study Group		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 264 (0.00%)		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 September 2013	<ul style="list-style-type: none"><li>• Eligibility criteria have been added and modified for one or more of the following reasons: to respond to FDA/CBER comments, to increase the homogeneity of the subject population and/or to increase safety of the subjects.</li><li>• As per CBER's request, any medical condition including the occurrence of a new pIMD or the exacerbation of an existing pIMD that, in the opinion of the investigator, exposes the subject to unacceptable risk from subsequent vaccination, constitutes contraindications to further administration of HZ/su vaccine. The change is not in response to any safety concern identified by GSK arising from an event or series of events in any completed or ongoing clinical studies that have been or are being conducted as part of GSK's Zoster vaccine program or in studies conducted as part of other GSK vaccine programs.</li><li>• To add the endpoint of allograft dysfunction, as measured by serum creatinine, to the safety objectives (co-primary and secondary).</li><li>• Secondary to limitations in number of designated CMI sites, allocation of subjects into the Cell-Mediated Immunity (CMI) sub-cohort will be based on the first eligible subjects enrolled at the designated sites until the targeted subject number is reached.</li><li>• To add allograft instability as contraindication to subsequent vaccination.</li></ul>

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported