Study to Evaluate the Safety and Effectiveness of Zostavax™ in Subjects 50 - 59 Years of Age (V211-022)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00534248

First received: September 21, 2007
Last updated: August 11, 2015
Last verified: August 2015
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Purpose

This study will look at how well Zostavax™ works in preventing shingles in participants ages 50-59 years old.

Condition	Intervention	Phase
Shingles	Biological: Zoster Vaccine, Live (Zostavax™) Biological: Comparator: Placebo	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Prevention

Official Title: A Phase III Clinical Trial to Evaluate the Efficacy, Immunogenicity, Safety and Tolerability of Zostavax™ in Subjects 50-59 Years of Age

Resource links provided by NLM:

MedlinePlus related topics: Shingles

Drug Information available for: Herpes Zoster Vaccine

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Incidence of Confirmed Herpes Zoster (HZ) Cases by Vaccination Group [Time Frame: 2 Years] [Designated as safety issue: No]

Incidence rate of HZ cases was defined as the number of confirmed HZ cases per 1000 person-years of follow-up following vaccination. Vaccine efficacy for HZ was defined as the relative reduction in incidence rate of HZ in the group that received Zostavax™ compared with the group that received placebo based on the intent-to-treat population.

Secondary Outcome Measures:

- Varicella-zoster Virus (VZV) Antibody Response at 6 Weeks Post Vaccination by Vaccination Group [Time Frame: 6 Weeks] [Designated as safety issue: No]

  VZV antibody response as measured by Glycoprotein Enzyme-Linked Immunosorbent Assay (gpELISA) in the group that received Zostavax™ compared with the group that received placebo, based on the random subcohort population.

- Number of Participants Reporting One or More Serious Adverse Experiences by Vaccination Group During the 42-day Postvaccination Follow-up Period [Time Frame: Through 42 days post-vaccination] [Designated as safety issue: Yes]

  A serious adverse event is defined as any adverse event that results in death, is life threatening, results in a persistent or significant disability/incapacity, results in hospitalization or prolongs an existing hospitalization, is a congenital anomaly/birth defect, is a cancer, is an overdose, or is considered an "other important medical event" based on medical judgement.

Enrollment:	22439
Study Start Date:	October 2007
Study Completion Date:	January 2010
Primary Completion Date:	January 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Zostavax™ Participants randomized to receive Zoster Vaccine, Live (Zostavax™).	Biological: Zoster Vaccine, Live (Zostavax™) A single dose 0.65 ml Zostavax™ (Live, attenuated Zoster Vaccine) was administered by subcutaneous injection on Day 1. Other Names: • V211 • Zostavax™
Placebo Comparator: Placebo Participants randomized to receive Placebo.	Biological: Comparator: Placebo A single dose of 0.65 ml Placebo (A vaccine stabilizer of Zostavax™ with no live virus) was administered by subcutaneous injection on Day 1.

Eligibility

Ages Eligible for Study:	50 Years to 59 Years
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- Must be between 50 - 59 years of age
- No fever on day of vaccination
- Females of reproductive potential must be willing to use acceptable form of birth control

Exclusion Criteria:

- Have received chicken pox or shingles vaccine
- Have already had shingles
- Have recently had another vaccination
- Pregnant or breast feeding. Have participated in another research study in the last 30 days
- You are taking certain antiviral drugs
- History of allergic reaction to any vaccine component, including gelatin or neomycin

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00534248

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information EXIT

Merck: Patient & Caregiver U.S. Product Web Site EXIT

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Gilbert PB, Gabriel EE, Miao X, Li X, Su SC, Parrino J, Chan IS. Fold rise in antibody titers by measured by glycoprotein-based enzyme-linked immunosorbent assay is an excellent correlate of protection for a herpes zoster vaccine, demonstrated via the vaccine efficacy curve. J Infect Dis. 2014 Nov 15;210(10):1573-81. doi: 10.1093/infdis/jiu279. Epub 2014 May 13.

Levin MJ, Schmader KE, Gnann JW, McNeil SA, Vesikari T, Betts RF, Keay S, Stek JE, Bundick ND, Su SC, Zhao Y, Li X, Chan IS, Annunziato PW, Parrino J. Varicella-zoster virus-specific antibody responses in 50-59-year-old recipients of zoster vaccine. J Infect Dis. 2013 Nov 1;208(9):1386-90. doi: 10.1093/infdis/jit342. Epub 2013 Aug 1.

Schmader KE, Levin MJ, Gnann JW Jr, McNeil SA, Vesikari T, Betts RF, Keay S, Stek JE, Bundick ND, Su SC, Zhao Y, Li X, Chan IS, Annunziato PW, Parrino J. Efficacy, safety, and tolerability of herpes zoster vaccine in persons aged 50-59 years. Clin Infect Dis. 2012 Apr;54(7):922-8. doi: 10.1093/cid/cir970. Epub 2012 Jan 30.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00534248 History of Changes
Other Study ID Numbers:	V211-022 2007_551
Study First Received:	September 21, 2007
Results First Received:	January 4, 2011
Last Updated:	August 11, 2015
Health Authority:	United States: Food and Drug Administration

ClinicalTrials.gov processed this record on April 20, 2016

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First received: September 21, 2007
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Results First Received: January 4, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Prevention
Condition:	Shingles
Interventions:	Biological: Zoster Vaccine, Live (Zostavax™) Biological: Comparator: Placebo

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description

Zostavax™	Participants randomized to receive a single 0.65 ml subcutaneous injection of Zoster Vaccine, Live (Zostavax™).
Placebo	Participants randomized to receive a single 0.65 ml subcutaneous injection of placebo.

Participant Flow: Overall Study

	Zostavax™	Placebo
STARTED	**11211**	**11228**
VACCINATED	**11186**	**11210**
COMPLETED	**10550**	**10555**
NOT COMPLETED	**661**	**673**
Adverse Event	**19**	**29**
Lost to Follow-up	**353**	**375**
Other protocol specified criteria	**13**	**3**
Physician Decision	**10**	**7**
Protocol Violation	**3**	**4**
Withdrawal by Subject	**263**	**255**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Zostavax™	Participants randomized to receive a single 0.65 ml subcutaneous injection of Zoster Vaccine, Live (Zostavax™).
Placebo	Participants randomized to receive a single 0.65 ml subcutaneous injection of placebo.
Total	Total of all reporting groups

Baseline Measures

	Zostavax™	Placebo	Total
Number of Participants [units: participants]	**11211**	**11228**	**22439**
Age [units: years] Mean (Standard Deviation)	**54.9 (2.8)**	**54.8 (2.8)**	**54.8 (2.8)**
Gender			

[units: participants]			
Female	6913	6972	13885
Male	4298	4256	8554

Outcome Measures

Hide All Outcome Measures

1. Primary: Incidence of Confirmed Herpes Zoster (HZ) Cases by Vaccination Group [Time Frame: 2 Years]

Measure Type	Primary
Measure Title	Incidence of Confirmed Herpes Zoster (HZ) Cases by Vaccination Group
Measure Description	Incidence rate of HZ cases was defined as the number of confirmed HZ cases per 1000 person-years of follow-up following vaccination. Vaccine efficacy for HZ was defined as the relative reduction in incidence rate of HZ in the group that received Zostavax™ compared with the group that received placebo based on the intent-to-treat population.
Time Frame	2 Years
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent-to-treat population defined as all participants randomized in the study according to the planned treatment, Zostavax or placebo, they were assigned.

Reporting Groups

	Description
Zostavax™	Participants randomized to receive a single 0.65 ml subcutaneous injection of Zoster Vaccine, Live (Zostavax™).
Placebo	Participants randomized to receive a single 0.65 ml subcutaneous injection of placebo.

Measured Values

	Zostavax™	Placebo
Number of Participants Analyzed [units: participants]	**11211**	**11228**
Incidence of Confirmed Herpes Zoster (HZ) Cases by Vaccination Group [units: number of HZ cases/1000 person-years] Mean (95% Confidence Interval)	**1.994 (1.346 to 2.847)**	**6.596 (5.361 to 8.030)**

Statistical Analysis 1 for Incidence of Confirmed Herpes Zoster (HZ) Cases by Vaccination Group

Groups [1]	All groups
Method [2]	Conditional Exact Method
P Value [3]	<.001
[4]	.698

point estimate	
95% Confidence Interval	.541 to .806

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Vaccine efficacy with respect to HZ was defined as the relative reduction in incidence rate of HZ point estimate (95% CI) calculated as 1 minus the ratio of the estimated incidence rates of HZ in the zoster vaccine group and the placebo group.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	The point estimate was for vaccine efficacy with respect to incidence of HZ.

2. Secondary: Varicella-zoster Virus (VZV) Antibody Response at 6 Weeks Post Vaccination by Vaccination Group [Time Frame: 6 Weeks]

Measure Type	Secondary
Measure Title	Varicella-zoster Virus (VZV) Antibody Response at 6 Weeks Post Vaccination by Vaccination Group
Measure Description	VZV antibody response as measured by Glycoprotein Enzyme-Linked Immunosorbent Assay (gpELISA) in the group that received Zostavax™ compared with the group that received placebo, based on the random subcohort population.
Time Frame	6 Weeks
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Random subcohort population included 10% of all randomized participants randomly selected for immunogenicity assay, were vaccinated (according to actual treatment received), had results at prevaccination and at 6 weeks postvaccination. Results from participants with protocol violations that may impact the immunogenicity analysis were excluded.

Reporting Groups

	Description
Zostavax™	Participants randomized to receive a single 0.65 ml subcutaneous injection of Zoster Vaccine, Live (Zostavax™).
Placebo	Participants randomized to receive a single 0.65 ml subcutaneous injection of placebo.

Measured Values

	Zostavax™	**Placebo**
Number of Participants Analyzed [units: participants]	**1088**	**1087**
Varicella-zoster Virus (VZV) Antibody Response at 6 Weeks Post Vaccination by Vaccination Group [units: gpELISA units/mL] Mean (95% Confidence Interval)	**660.0 (624.7 to 697.2)**	**293.1 (274.7 to 312.6)**

Statistical Analysis 1 for Varicella-zoster Virus (VZV) Antibody Response at 6 Weeks Post Vaccination by Vaccination Group

Groups [1]	All groups
Method [2]	linear mixed longitudinal analysis model
P Value [3]	<.001
geometric mean titre ratio [4]	2.3
95% Confidence Interval	2.2 to 2.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[3]	Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance:
	No text entered.
[4]	Other relevant estimation information:
	No text entered.

3. Secondary: Number of Participants Reporting One or More Serious Adverse Experiences by Vaccination Group During the 42-day Postvaccination Follow-up Period [Time Frame: Through 42 days post-vaccination]

Measure Type	Secondary
Measure Title	Number of Participants Reporting One or More Serious Adverse Experiences by Vaccination Group During the 42-day Postvaccination Follow-up Period
Measure Description	A serious adverse event is defined as any adverse event that results in death, is life threatening, results in a persistent or significant disability/incapacity, results in hospitalization or prolongs an existing hospitalization, is a congenital anomaly/birth defect, is a cancer, is an overdose, or is considered an "other important medical event" based on medical judgement.
Time Frame	Through 42 days post-vaccination
Safety Issue	Yes

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
All participants who were vaccinated according to actual treatment received (Zostavax or placebo) and had safety follow-up.

Reporting Groups

	Description
Zostavax™	Participants randomized to receive a single 0.65 ml subcutaneous injection of Zoster Vaccine, Live (Zostavax™).
Placebo	Participants randomized to receive a single 0.65 ml subcutaneous injection of placebo.

Measured Values

	Zostavax™	Placebo
Number of Participants Analyzed [units: participants]	**11094**	**11116**
Number of Participants Reporting One or More Serious Adverse Experiences by Vaccination Group During the 42-day Postvaccination Follow-up Period [units: participants]	**69**	**61**

Statistical Analysis 1 for Number of Participants Reporting One or More Serious Adverse Experiences by Vaccination Group During the 42-day Postvaccination Follow-up Period

Groups [1]	All groups
Relative Risk [2]	1.133
95% Confidence Interval	.805 to 1.595

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	Analysis of proportion of participants reporting one or more serious adverse experiences reported within 42 days postvaccination.
[2]	Other relevant estimation information:
	No text entered.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Serious adverse events (SAEs) are presented that occurred from Day 1 to 182 postvaccination. Deaths that occurred any time during the study are also included. Non-serious AEs are presented for events that occurred from Day 1 to 42 postvaccination.
Additional Description	AEs and SAEs were reported in participants who were vaccinated according to actual treatment received (Zostavax or placebo) and had safety follow-up.

Reporting Groups

	Description
Zostavax™	Participants randomized to receive a single 0.65 ml subcutaneous injection of Zoster Vaccine, Live (Zostavax™).
Placebo	Participants randomized to receive a single 0.65 ml subcutaneous injection of placebo.

Serious Adverse Events

	Zostavax™	Placebo
Total, serious adverse events		
# participants affected / at risk	**243/11094 (2.19%)**	**233/11116 (2.10%)**
Blood and lymphatic system disorders		

Anaemia † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Nephrogenic anaemia † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Splenic infarction † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Cardiac disorders		
Acute myocardial infarction † 1		
# participants affected / at risk	**3/11094 (0.03%)**	**2/11116 (0.02%)**
# events	**3**	**2**
Angina pectoris † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**0/11116 (0.00%)**
# events	**2**	**0**
Angina unstable † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Arteriosclerosis coronary artery † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**3/11116 (0.03%)**
# events	**1**	**3**
Atrial fibrillation † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**6/11116 (0.05%)**
# events	**2**	**6**
Bradycardia † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Cardiac arrest † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Cardiac failure congestive † 1		
# participants affected / at risk	**5/11094 (0.05%)**	**1/11116 (0.01%)**
# events	**5**	**1**
Cardio-respiratory arrest † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Cardiomegaly † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Cardiomyopathy † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Coronary artery disease † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**2/11116 (0.02%)**

# events	2	2
Coronary artery occlusion † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Coronary artery stenosis † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Coronary artery thrombosis † 1		
# participants affected / at risk	0/11094 (0.00%)	2/11116 (0.02%)
# events	0	2
Hypertensive heart disease † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Hypertrophic cardiomyopathy † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Mitral valve prolapse † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Myocardial infarction † 1		
# participants affected / at risk	4/11094 (0.04%)	5/11116 (0.04%)
# events	4	5
Stress cardiomyopathy † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Supraventricular tachycardia † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Tachycardia † 1		
# participants affected / at risk	3/11094 (0.03%)	0/11116 (0.00%)
# events	3	0
Ventricular tachycardia † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Congenital, familial and genetic disorders		
Congenital diaphragmatic hernia † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Porphyria acute † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Ear and labyrinth disorders		
Deafness neurosensory † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1

Vertigo † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Vertigo positional † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Endocrine disorders		
Goitre † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Hyperparathyroidism † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Thyroiditis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Eye disorders		
Diplopia † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Retinal vein occlusion † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Gastrointestinal disorders		
Abdominal hernia † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**0/11116 (0.00%)**
# events	**2**	**0**
Abdominal pain upper † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Anal fistula † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Ascites † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Colitis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Colitis ulcerative † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Colonic polyp † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**

Constipation † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Diverticulum † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Duodenal ulcer haemorrhage † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Gastrointestinal haemorrhage † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Haematemesis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Inguinal hernia † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Intestinal obstruction † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**0/11116 (0.00%)**
# events	**3**	**0**
Large intestinal obstruction † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Large intestine perforation † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Mechanical ileus † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Oesophageal achalasia † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**2**	**0**
Oesophageal ulcer † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Oesophageal varices haemorrhage † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Pancreatic disorder † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Pancreatitis † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**4/11116 (0.04%)**
# events	**0**	**4**
† 1		

Pancreatitis acute		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Peritonitis † [1]		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Rectal prolapse † [1]		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Small intestinal obstruction † [1]		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Upper gastrointestinal haemorrhage † [1]		
# participants affected / at risk	**0/11094 (0.00%)**	**2/11116 (0.02%)**
# events	**0**	**2**
General disorders		
Chest discomfort † [1]		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Chest pain † [1]		
# participants affected / at risk	**7/11094 (0.06%)**	**7/11116 (0.06%)**
# events	**7**	**7**
Death † [1]		
# participants affected / at risk	**3/11094 (0.03%)**	**2/11116 (0.02%)**
# events	**3**	**2**
Hernia obstructive † [1]		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Impaired healing † [1]		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Inflammation † [1]		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Non-cardiac chest pain † [1]		
# participants affected / at risk	**5/11094 (0.05%)**	**7/11116 (0.06%)**
# events	**5**	**7**
Pyrexia † [1]		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Hepatobiliary disorders		
Alcoholic liver disease † [1]		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Cholangitis † [1]		

# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Cholecystitis † 1		
# participants affected / at risk	3/11094 (0.03%)	3/11116 (0.03%)
# events	3	3
Cholecystitis acute † 1		
# participants affected / at risk	2/11094 (0.02%)	0/11116 (0.00%)
# events	2	0
Cholelithiasis † 1		
# participants affected / at risk	2/11094 (0.02%)	3/11116 (0.03%)
# events	2	3
Hepatic cirrhosis † 1		
# participants affected / at risk	0/11094 (0.00%)	2/11116 (0.02%)
# events	0	2
Hepatic failure † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Perforation bile duct † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Immune system disorders		
Allergic oedema † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Anaphylactic reaction † 1		
# participants affected / at risk	2/11094 (0.02%)	1/11116 (0.01%)
# events	2	1
Anaphylactic shock † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Infections and infestations		
Abdominal abscess † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Appendicitis † 1		
# participants affected / at risk	6/11094 (0.05%)	7/11116 (0.06%)
# events	6	7
Arthritis bacterial † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Bursitis infective staphylococcal † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Cellulitis † 1		
# participants affected / at risk	2/11094 (0.02%)	5/11116 (0.04%)

# events	2	5
Device related infection † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Diabetic gangrene † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Diverticulitis † 1		
# participants affected / at risk	3/11094 (0.03%)	2/11116 (0.02%)
# events	3	2
Endocarditis bacterial † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Epidemic nephropathy † 1		
# participants affected / at risk	2/11094 (0.02%)	1/11116 (0.01%)
# events	2	1
Erysipelas † 1		
# participants affected / at risk	4/11094 (0.04%)	2/11116 (0.02%)
# events	4	2
Furuncle † 1		
# participants affected / at risk	1/11094 (0.01%)	1/11116 (0.01%)
# events	1	1
Gastroenteritis † 1		
# participants affected / at risk	3/11094 (0.03%)	3/11116 (0.03%)
# events	3	3
Gastroenteritis viral † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Infection † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Lobar pneumonia † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Localised infection † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Meningitis aseptic † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Osteomyelitis † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Peritonitis bacterial † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1

Pharyngeal abscess † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Pneumonia † 1		
# participants affected / at risk	**4/11094 (0.04%)**	**8/11116 (0.07%)**
# events	**4**	**8**
Pneumonia bacterial † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Post procedural infection † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Pyelonephritis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Pyelonephritis acute † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**2/11116 (0.02%)**
# events	**1**	**2**
Respiratory tract infection † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Sepsis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Sinusitis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Superinfection † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Upper respiratory tract infection † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Urosepsis † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Vestibular neuronitis † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Injury, poisoning and procedural complications		
Accidental overdose † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**2/11116 (0.02%)**
# events	**0**	**2**
Alcohol poisoning † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**

# events	1	1
Ankle fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	4/11116 (0.04%)
# events	1	4
Bladder injury † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Brain contusion † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Cervical vertebral fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Concussion † 1		
# participants affected / at risk	2/11094 (0.02%)	0/11116 (0.00%)
# events	2	0
Contusion † 1		
# participants affected / at risk	2/11094 (0.02%)	0/11116 (0.00%)
# events	2	0
Device failure † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Drug toxicity † 1		
# participants affected / at risk	0/11094 (0.00%)	2/11116 (0.02%)
# events	0	2
Facial bones fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Foot fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Hand fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	1/11116 (0.01%)
# events	1	1
Head injury † 1		
# participants affected / at risk	2/11094 (0.02%)	1/11116 (0.01%)
# events	2	1
Hip fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Humerus fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Incisional hernia † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)

# events	1	0
Joint dislocation † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Limb traumatic amputation † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	2	0
Meniscus lesion † 1		
# participants affected / at risk	2/11094 (0.02%)	1/11116 (0.01%)
# events	2	1
Overdose † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Postoperative ileus † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Rib fracture † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Skull fracture † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Soft tissue injury † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Spinal compression fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Splenic rupture † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Stent occlusion † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Subdural haemorrhage † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Synovial rupture † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Tendon rupture † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Tibia fracture † 1		
# participants affected / at risk	1/11094 (0.01%)	1/11116 (0.01%)
# events	1	1

Traumatic brain injury † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Ureteric injury † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Urinary retention postoperative † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Wound † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Wound complication † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Wrist fracture † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**2/11116 (0.02%)**
# events	**0**	**2**
Metabolism and nutrition disorders		
Dehydration † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Diabetes mellitus † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Diabetes mellitus inadequate control † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Hyperglycaemia † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**2/11116 (0.02%)**
# events	**1**	**2**
Hypoglycaemia † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**2/11116 (0.02%)**
# events	**0**	**2**
Hypokalaemia † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Hyponatraemia † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**2/11116 (0.02%)**
# events	**0**	**3**
Obesity † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Type 2 diabetes mellitus † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**

# events	0	1
Musculoskeletal and connective tissue disorders		
Arthralgia † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Arthritis † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Back pain † 1		
# participants affected / at risk	3/11094 (0.03%)	1/11116 (0.01%)
# events	3	1
Intervertebral disc degeneration † 1		
# participants affected / at risk	2/11094 (0.02%)	0/11116 (0.00%)
# events	2	0
Intervertebral disc protrusion † 1		
# participants affected / at risk	4/11094 (0.04%)	2/11116 (0.02%)
# events	4	2
Joint effusion † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Musculoskeletal chest pain † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Osteoarthritis † 1		
# participants affected / at risk	2/11094 (0.02%)	2/11116 (0.02%)
# events	2	2
Osteonecrosis † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Patellofemoral pain syndrome † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Rhabdomyolysis † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Rotator cuff syndrome † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Spinal column stenosis † 1		
# participants affected / at risk	1/11094 (0.01%)	1/11116 (0.01%)
# events	1	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Adenocarcinoma † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)

# events	1	0
Anal cancer † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Basal cell carcinoma † 1		
# participants affected / at risk	14/11094 (0.13%)	10/11116 (0.09%)
# events	14	10
Benign lung neoplasm † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Benign neoplasm of cervix uteri † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Bladder cancer † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Borderline ovarian tumour † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Breast cancer † 1		
# participants affected / at risk	10/11094 (0.09%)	7/11116 (0.06%)
# events	10	7
Breast cancer in situ † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Breast cancer stage II † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Bronchial carcinoma † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Chronic lymphocytic leukaemia † 1		
# participants affected / at risk	1/11094 (0.01%)	1/11116 (0.01%)
# events	1	1
Colon cancer † 1		
# participants affected / at risk	2/11094 (0.02%)	1/11116 (0.01%)
# events	2	1
Endometrial cancer metastatic † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Endometrial cancer stage III † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Fallopian tube cancer † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1

Fibroadenoma of breast † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Gastric cancer † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Hepatic cancer metastatic † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Hepatic neoplasm malignant † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Lung neoplasm malignant † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**0/11116 (0.00%)**
# events	**2**	**0**
Lymphoma † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Malignant melanoma † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**2/11116 (0.02%)**
# events	**0**	**2**
Meningioma † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Metastases to liver † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Metastatic neoplasm † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Multiple myeloma † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Myelodysplastic syndrome † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Nasal cavity cancer † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Neoplasm malignant † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Neurilemmoma benign † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**

Non-small cell lung cancer † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Oesophageal carcinoma † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Ovarian cancer † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Ovarian epithelial cancer † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Pancreatic carcinoma † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Pancreatic carcinoma metastatic † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Prostate cancer † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**2/11116 (0.02%)**
# events	**1**	**2**
Rectal cancer † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Squamous cell carcinoma † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Squamous cell carcinoma of skin † 1		
# participants affected / at risk	**3/11094 (0.03%)**	**4/11116 (0.04%)**
# events	**3**	**4**
Throat cancer † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Thyroid cancer † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**1/11116 (0.01%)**
# events	**2**	**1**
Uterine cancer † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Uterine leiomyoma † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Waldenstrom's macroglobulinaemia † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Nervous system disorders		

Brain stem infarction † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Cerebellar infarction † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Cerebral infarction † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Cerebrovascular accident † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**3/11116 (0.03%)**
# events	**0**	**3**
Cervical root pain † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Cervicobrachial syndrome † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Convulsion † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Cubital tunnel syndrome † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Encephalopathy † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Epilepsy † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Facial palsy † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**0/11116 (0.00%)**
# events	**2**	**0**
Headache † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**2/11116 (0.02%)**
# events	**0**	**2**
Hypoaesthesia † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Intracranial aneurysm † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Migraine † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**

Migraine with aura † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Myasthenia gravis † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Nerve compression † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Neuropathy peripheral † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Paraesthesia † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Parkinson's disease † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Transient ischaemic attack † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**2/11116 (0.02%)**
# events	**2**	**2**
Psychiatric disorders		
Acute psychosis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Affective disorder † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Alcohol abuse † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**0/11116 (0.00%)**
# events	**2**	**0**
Alcohol withdrawal syndrome † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**3/11116 (0.03%)**
# events	**1**	**6**
Completed suicide † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**3/11116 (0.03%)**
# events	**0**	**3**
Confusional state † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Depression † 1		
# participants affected / at risk	**4/11094 (0.04%)**	**1/11116 (0.01%)**
# events	**4**	**1**
Depression suicidal † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**

# events	0	1
Drug dependence † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	2	0
Major depression † 1		
# participants affected / at risk	2/11094 (0.02%)	2/11116 (0.02%)
# events	2	2
Post-traumatic stress disorder † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Suicidal behaviour † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Suicidal ideation † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Suicide attempt † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Renal and urinary disorders		
Calculus urinary † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Nephrolithiasis † 1		
# participants affected / at risk	1/11094 (0.01%)	2/11116 (0.02%)
# events	1	2
Renal colic † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Renal failure acute † 1		
# participants affected / at risk	2/11094 (0.02%)	1/11116 (0.01%)
# events	2	1
Renal failure chronic † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Renal infarct † 1		
# participants affected / at risk	0/11094 (0.00%)	1/11116 (0.01%)
# events	0	1
Reproductive system and breast disorders		
Benign prostatic hyperplasia † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0
Endometrial hyperplasia † 1		
# participants affected / at risk	1/11094 (0.01%)	0/11116 (0.00%)
# events	1	0

Uterine prolapse † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Respiratory, thoracic and mediastinal disorders		
Acute respiratory distress syndrome † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Asthma † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**3/11094 (0.03%)**	**2/11116 (0.02%)**
# events	**3**	**2**
Haemothorax † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Laryngeal cyst † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Pneumothorax † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Pulmonary arterial hypertension † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Pulmonary embolism † 1		
# participants affected / at risk	**3/11094 (0.03%)**	**3/11116 (0.03%)**
# events	**3**	**3**
Respiratory failure † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Skin and subcutaneous tissue disorders		
Angioedema † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Psoriasis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Skin ulcer † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Vascular disorders		
Aortic stenosis † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**

Arterial occlusive disease † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**
Deep vein thrombosis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Haemorrhage † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**1/11116 (0.01%)**
# events	**1**	**1**
Hypertension † 1		
# participants affected / at risk	**2/11094 (0.02%)**	**1/11116 (0.01%)**
# events	**2**	**1**
Hypertensive crisis † 1		
# participants affected / at risk	**1/11094 (0.01%)**	**0/11116 (0.00%)**
# events	**1**	**0**
Orthostatic hypotension † 1		
# participants affected / at risk	**0/11094 (0.00%)**	**1/11116 (0.01%)**
# events	**0**	**1**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 12.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	Serious adverse events (SAEs) are presented that occurred from Day 1 to 182 postvaccination. Deaths that occurred any time during the study are also included. Non-serious AEs are presented for events that occurred from Day 1 to 42 postvaccination.
Additional Description	AEs and SAEs were reported in participants who were vaccinated according to actual treatment received (Zostavax or placebo) and had safety follow-up.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Zostavax™	Participants randomized to receive a single 0.65 ml subcutaneous injection of Zoster Vaccine, Live (Zostavax™).
Placebo	Participants randomized to receive a single 0.65 ml subcutaneous injection of placebo.

Other Adverse Events

	Zostavax™	**Placebo**
Total, other (not including serious) adverse events		
# participants affected / at risk	**7228/11094 (65.15%)**	**2183/11116 (19.64%)**

General disorders		
Injection site erythema † 1		
# participants affected / at risk	**5351/11094 (48.23%)**	**483/11116 (4.35%)**
# events	**5409**	**484**
Injection site pain † 1		
# participants affected / at risk	**6005/11094 (54.13%)**	**1025/11116 (9.22%)**
# events	**6276**	**1052**
Injection site pruritus † 1		
# participants affected / at risk	**1287/11094 (11.60%)**	**78/11116 (0.70%)**
# events	**1307**	**84**
Injection site swelling † 1		
# participants affected / at risk	**4500/11094 (40.56%)**	**309/11116 (2.78%)**
# events	**4549**	**311**
Nervous system disorders		
Headache † 1		
# participants affected / at risk	**1041/11094 (9.38%)**	**917/11116 (8.25%)**
# events	**1509**	**1357**

† Events were collected by systematic assessment

1 Term from vocabulary, MedDRA 12.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Vice President of Late Stage Development
Organization: Merck Sharp & Dohme Corp
e-mail: ClinicalTrialsDisclosure@merck.com

Publications automatically indexed to this study by ClinicalTrials.gov Identifier (NCT Number):

Gilbert PB, Gabriel EE, Miao X, Li X, Su SC, Parrino J, Chan IS. Fold rise in antibody titers by measured by glycoprotein-based enzyme-linked immunosorbent assay is an excellent correlate of protection for a herpes zoster vaccine, demonstrated via the vaccine efficacy curve. J Infect Dis. 2014 Nov 15;210(10):1573-81. doi: 10.1093/infdis/jiu279. Epub 2014 May 13.

Levin MJ, Schmader KE, Gnann JW, McNeil SA, Vesikari T, Betts RF, Keay S, Stek JE, Bundick ND, Su SC, Zhao Y, Li X, Chan IS, Annunziato PW, Parrino J. Varicella-zoster virus-specific antibody responses in 50-59-year-old recipients of zoster vaccine. J Infect Dis. 2013 Nov 1;208(9):1386-90. doi: 10.1093/infdis/jit342. Epub 2013 Aug 1.

Schmader KE, Levin MJ, Gnann JW Jr, McNeil SA, Vesikari T, Betts RF, Keay S, Stek JE, Bundick ND, Su SC, Zhao Y, Li X, Chan IS, Annunziato PW, Parrino J. Efficacy, safety, and tolerability of herpes zoster vaccine in persons aged 50-59 years. Clin Infect Dis. 2012 Apr;54(7):922-8. doi: 10.1093/cid/cir970. Epub 2012 Jan 30.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00534248 History of Changes
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Results First Received:	January 4, 2011
Last Updated:	August 11, 2015
Health Authority:	United States: Food and Drug Administration

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