A Study of an Investigational Zoster Vaccine in Subjects With a History of Varicella (Chickenpox) Given Concomitantly With Another Vaccine (V211-011)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00231816

First received: September 30, 2005
Last updated: September 2, 2015
Last verified: September 2015
History of Changes

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Purpose

The purpose of this study is to determine whether the investigational zoster vaccine has a comparable immune response (the body's ability to protect against disease) and safety profile when given concomitantly with another vaccine.

Condition	Intervention	Phase
Herpes Zoster	Biological: ZOSTAVAX™ (concomitant) Biological: Comparator: Influenza Vaccine Biological: ZOSTAVAX™ (Nonconcomitant)	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 Double-Blind, Randomized, Multicenter Study to Evaluate the Safety, Tolerability, and Immunogenicity of V211 Administered Concomitantly Versus Nonconcomitantly With Influenza Virus Vaccine (Inactivated)

Resource links provided by NLM:

MedlinePlus related topics: Chickenpox Flu Shingles

Drug Information available for: Herpes Zoster Vaccine Influenza Vaccines

U.S. FDA Resources

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

Primary Outcome Measures:

- Varicella-zoster Virus (VZV) Glycoprotein Enzyme-linked Immunosorbent Assay (gpELISA) Antibody Responses [Time Frame: 4 weeks] [Designated as safety issue: No]

  The Geometric mean titer (GMT) of the VZV glycoprotein enzyme-linked immunosorbent assay (gpELISA) antibody responses at Week 4 postvaccination in participants who received ZOSTAVAX™ concomitantly with influenza vaccine was compared to that in subjects who received influenza vaccine and ZOSTAVAX™ nonconcomitantly.

Other Outcome Measures:

- Geometric Mean Fold Rise (GMFR) in VZV gpELISA Antibody Titers From Prevaccination to 4 Weeks Postvaccination [Time Frame: prevaccination to 4 weeks postvaccination] [Designated as safety issue: No]

  GMFR of the VZV gpELISA antibody titers from prevaccination

  to 4 weeks postvaccination when ZOSTAVAX™ is administered concomitantly with influenza vaccine

- Geometric Mean Titers (GMTs) of H1N1 Strain Antibody Responses at 4 Weeks Postvaccination [Time Frame: 4 weeks postvaccination] [Designated as safety issue: No]

  GMT of the H1N1 strain antibody responses at 4 weeks postvaccination in participants who receive ZOSTAVAX™ concomitantly with influenza vaccine and those who receive ZOSTAVAX™ and influenza vaccine nonconcomitantly

- GMTs of H3N2 Strain Antibody Responses at 4 Weeks Postvaccination [Time Frame: 4 weeks postvaccination] [Designated as safety issue: No]

  GMT of the H3N2 strain antibody responses at 4 weeks postvaccination in participants who receive ZOSTAVAX™ concomitantly with influenza vaccine and those who receive ZOSTAVAX™ and influenza vaccine nonconcomitantly

- GMTs of B Strain Antibody Responses at 4 Weeks Postvaccination [Time Frame: 4 weeks postvaccination] [Designated as safety issue: No]

  GMT of the B strain antibody responses at 4 weeks postvaccination in participants who receive ZOSTAVAX™ concomitantly with influenza vaccine and those who receive ZOSTAVAX™ and influenza vaccine nonconcomitantly

Enrollment:	763
Study Start Date:	September 2005
Study Completion Date:	March 2006
Primary Completion Date:	March 2006 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Concomitant Zostavax concomitantly with influenza vaccine on Day 1, placebo at week 4	Biological: ZOSTAVAX™ (concomitant) a single administration of 0.65 mL subcutaneous injection of zoster vaccine live on Day 1 and placebo at Week 4 Other Name: V211 Biological: Comparator: Influenza Vaccine a single administration of 0.5 mL intramuscular injection of influenza vaccine (inactivated) at Day 1 Other Name: Fluzone, Vaxigrip
Experimental: Nonconcomitant Influenza vaccine and Zostavax placebo on Day 1, Zostavax at week 4	Biological: Comparator: Influenza Vaccine a single administration of 0.5 mL intramuscular injection of influenza vaccine (inactivated) at Day 1 Other Name: Fluzone, Vaxigrip Biological: ZOSTAVAX™ (Nonconcomitant) Placebo injection on Day 1 and a single administration of 0.65 mL subcutaneous injection of zoster vaccine live at Week 4

Eligibility

Ages Eligible for Study:	50 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	Yes

Criteria

Inclusion Criteria:

- Adults 50 years of age or older

Exclusion Criteria:

- Prior history of Herpes Zoster (shingles)
- Prior receipt of varicella or zoster vaccine
- Immunosuppressed

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: NCT00231816

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Kerzner B, Murray AV, Cheng E, Ifle R, Harvey PR, Tomlinson M, Barben JL, Rarrick K, Stek JE, Chung MO, Schödel FP, Wang WW, Xu J, Chan IS, Silber JL, Schlienger K. Safety and immunogenicity profile of the concomitant administration of ZOSTAVAX and inactivated influenza vaccine in adults aged 50 and older. J Am Geriatr Soc. 2007 Oct;55(10):1499-507.

Sutradhar SC, Wang WW, Schlienger K, Stek JE, Xu J, Chan IS, Silber JL. Comparison of the levels of immunogenicity and safety of Zostavax in adults 50 to 59 years old and in adults 60 years old or older. Clin Vaccine Immunol. 2009 May;16(5):646-52. doi: 10.1128/CVI.00407-08. Epub 2009 Mar 4.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00231816 History of Changes
Other Study ID Numbers:	V211-011 2005_036
Study First Received:	September 30, 2005
Results First Received:	May 12, 2010
Last Updated:	September 2, 2015
Health Authority:	United States: Food and Drug Administration

Keywords provided by Merck Sharp & Dohme Corp.:
Prevention of Herpes Zoster

Additional relevant MeSH terms:
Herpes Zoster
DNA Virus Infections
Herpesviridae Infections
Virus Diseases

ClinicalTrials.gov processed this record on April 20, 2016

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Results First Received: May 12, 2010

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:	Herpes Zoster
Interventions:	Biological: ZOSTAVAX™ (concomitant) Biological: Comparator: Influenza Vaccine Biological: ZOSTAVAX™ (Nonconcomitant)

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
Participants were recruited at 13 sites in the United States and 7 sites in Europe. First Patient In (FPI): 23-SEP-2005; Last Patient Last Visit (LPLV): 08-MAR-2006

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
Concomitant Group	ZOSTAVAX™ 0.65 mL subcutaneous (SC) injection administered concomitantly with 0.5 mL intramuscular (IM) influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4
Nonconcomitant Group	Influenza vaccine 0.5 mL IM injection administerd with placebo injection on Day 1 and ZOSTAVAX™ 0.65 mL SC injection at Week 4

Participant Flow: Overall Study

	Concomitant Group	Nonconcomitant Group
STARTED	382	381
Vaccinated at Visit 1	382	380 [1]
Vaccinated at Visit 2	369	371
COMPLETED	366 [2]	369 [2]
NOT COMPLETED	16	12
Adverse Event	1	0
Lost to Follow-up	8	5
Protocol Violation	2	3
Withdrawal by Subject	3	3
Not Specified	2	1

[1] One participant was randomized but not vaccinated
[2] Participant received required vaccines and returned completed vaccination report cards at Visits 2&3

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
Concomitant Group	ZOSTAVAX™ 0.65 mL subcutaneous (SC) injection administered concomitantly with 0.5 mL intramuscular (IM) influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4
Nonconcomitant Group	Influenza vaccine 0.5 mL IM injection administerd with placebo injection on Day 1 and ZOSTAVAX™ 0.65 mL SC injection at Week 4
Total	Total of all reporting groups

Baseline Measures

	Concomitant Group	Nonconcomitant Group	Total

Number of Participants [units: participants]	**382**	**380**	**762**
Age [units: years] Mean (Standard Deviation)	**63.4 (7.99)**	**63.6 (8.24)**	**63.5 (8.11)**
Gender [units: participants]			
Female	**215**	**212**	**427**
Male	**167**	**168**	**335**
Race/Ethnicity, Customized [units: participants]			
African	**1**	**0**	**1**
Asian	**5**	**4**	**9**
Black	**106**	**100**	**206**
Hispanic American	**11**	**11**	**22**
Indian	**0**	**1**	**1**
Multiracial	**0**	**2**	**2**
Native American	**1**	**1**	**2**
White	**258**	**261**	**519**

Outcome Measures

Hide All Outcome Measures

1. Primary: Varicella-zoster Virus (VZV) Glycoprotein Enzyme-linked Immunosorbent Assay (gpELISA) Antibody Responses [Time Frame: 4 weeks]

Measure Type	Primary
Measure Title	Varicella-zoster Virus (VZV) Glycoprotein Enzyme-linked Immunosorbent Assay (gpELISA) Antibody Responses
Measure Description	The Geometric mean titer (GMT) of the VZV glycoprotein enzyme-linked immunosorbent assay (gpELISA) antibody responses at Week 4 postvaccination in participants who received ZOSTAVAX™ concomitantly with influenza vaccine was compared to that in subjects who received influenza vaccine and ZOSTAVAX™ nonconcomitantly.
Time Frame	4 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.
The primary analysis was based on the per protocol population defined as participants who had valid GMT results from samples obtained within the prespecified day ranges at Day 1, at Week 4, or at Week 8 postvaccination, and who did not meet any of the protocol violations prespecified in the statistical analysis plan (SAP).

Reporting Groups

	Description

Concomitant Group	ZOSTAVAX™ 0.65 mL subcutaneous (SC) injection administered concomitantly with 0.5 mL intramuscular (IM) influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4
Nonconcomitant Group	Influenza vaccine 0.5 mL IM injection administerd with placebo injection on Day 1 and ZOSTAVAX™ 0.65 mL SC injection at Week 4

Measured Values

	Concomitant Group	Nonconcomitant Group
Number of Participants Analyzed [units: participants]	**361**	**366**
Varicella-zoster Virus (VZV) Glycoprotein Enzyme-linked Immunosorbent Assay (gpELISA) Antibody Responses [units: gpELISA units/mL] Geometric Mean (95% Confidence Interval)	**553.5 (499.0 to 613.9)**	**588.7 (531.9 to 651.5)**

No statistical analysis provided for Varicella-zoster Virus (VZV) Glycoprotein Enzyme-linked Immunosorbent Assay (gpELISA) Antibody Responses

2. Other Pre-specified: Geometric Mean Fold Rise (GMFR) in VZV gpELISA Antibody Titers From Prevaccination to 4 Weeks Postvaccination [Time Frame: prevaccination to 4 weeks postvaccination]

Measure Type	Other Pre-specified
Measure Title	Geometric Mean Fold Rise (GMFR) in VZV gpELISA Antibody Titers From Prevaccination to 4 Weeks Postvaccination
Measure Description	GMFR of the VZV gpELISA antibody titers from prevaccination to 4 weeks postvaccination when ZOSTAVAX™ is administered concomitantly with influenza vaccine
Time Frame	prevaccination to 4 weeks postvaccination
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.
The analysis was based on the per protocol population defined as participants who had valid GMFR results from samples obtained within the prespecified day ranges at Day 1, at Week 4, or at Week 8 postvaccination, and who did not meet any of the protocol violations prespecified in the statistical analysis plan (SAP)

Reporting Groups

	Description
Concomitant Group	ZOSTAVAX™ 0.65 mL SC injection administered comcomitantly with 0.5 mL IM influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4

Measured Values

	Concomitant Group
Number of Participants Analyzed [units: participants]	**354**
Geometric Mean Fold Rise (GMFR) in VZV gpELISA Antibody Titers From Prevaccination to 4 Weeks Postvaccination [units: ratio]	**2.1 (2.0 to 2.3)**

Geometric Mean (95% Confidence Interval)	

No statistical analysis provided for Geometric Mean Fold Rise (GMFR) in VZV gpELISA Antibody Titers From Prevaccination to 4 Weeks Postvaccination

3. Other Pre-specified: Geometric Mean Titers (GMTs) of H1N1 Strain Antibody Responses at 4 Weeks Postvaccination [Time Frame: 4 weeks postvaccination]

Measure Type	Other Pre-specified
Measure Title	Geometric Mean Titers (GMTs) of H1N1 Strain Antibody Responses at 4 Weeks Postvaccination
Measure Description	GMT of the H1N1 strain antibody responses at 4 weeks postvaccination in participants who receive ZOSTAVAX™ concomitantly with influenza vaccine and those who receive ZOSTAVAX™ and influenza vaccine nonconcomitantly
Time Frame	4 weeks postvaccination
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.
The analysis was based on the per protocol population defined as participants who had valid results from samples obtained within the prespecified day ranges at Day 1, at Week 4, or at Week 8 postvaccination, and who did not meet any of the protocol violations prespecified in the SAP.

Reporting Groups

	Description
Concomitant Group	ZOSTAVAX™ 0.65 mL subcutaneous (SC) injection administered concomitantly with 0.5 mL intramuscular (IM) influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4
Nonconcomitant Group	Influenza vaccine 0.5 mL IM injection administerd with placebo injection on Day 1 and ZOSTAVAX™ 0.65 mL SC injection at Week 4

Measured Values

	Concomitant Group	**Nonconcomitant Group**
Number of Participants Analyzed [units: participants]	**363**	**363**
Geometric Mean Titers (GMTs) of H1N1 Strain Antibody Responses at 4 Weeks Postvaccination [units: titers] Geometric Mean (95% Confidence Interval)	**122.9 (107.8 to 140.0)**	**134.2 (118.3 to 152.2)**

No statistical analysis provided for Geometric Mean Titers (GMTs) of H1N1 Strain Antibody Responses at 4 Weeks Postvaccination

4. Other Pre-specified: GMTs of H3N2 Strain Antibody Responses at 4 Weeks Postvaccination [Time Frame: 4 weeks postvaccination]

Measure Type	Other Pre-specified
Measure Title	GMTs of H3N2 Strain Antibody Responses at 4 Weeks Postvaccination

Measure Description	GMT of the H3N2 strain antibody responses at 4 weeks postvaccination in participants who receive ZOSTAVAX™ concomitantly with influenza vaccine and those who receive ZOSTAVAX™ and influenza vaccine nonconcomitantly
Time Frame	4 weeks postvaccination
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.
The analysis was based on the per protocol population defined as participants who had valid results from samples obtained within the prespecified day ranges at Day 1, at Week 4, or at Week 8 postvaccination, and who did not meet any of the protocol violations prespecified in the SAP.

Reporting Groups

	Description
Concomitant Group	ZOSTAVAX™ 0.65 mL subcutaneous (SC) injection administered concomitantly with 0.5 mL intramuscular (IM) influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4
Nonconcomitant Group	Influenza vaccine 0.5 mL IM injection administerd with placebo injection on Day 1 and ZOSTAVAX™ 0.65 mL SC injection at Week 4

Measured Values

	Concomitant Group	**Nonconcomitant Group**
Number of Participants Analyzed [units: participants]	**363**	**363**
GMTs of H3N2 Strain Antibody Responses at 4 Weeks Postvaccination [units: titers] Geometric Mean (95% Confidence Interval)	**162.7 (140.4 to 188.4)**	**150.5 (129.8 to 174.5)**

No statistical analysis provided for GMTs of H3N2 Strain Antibody Responses at 4 Weeks Postvaccination

5. Other Pre-specified: GMTs of B Strain Antibody Responses at 4 Weeks Postvaccination [Time Frame: 4 weeks postvaccination]

Measure Type	Other Pre-specified
Measure Title	GMTs of B Strain Antibody Responses at 4 Weeks Postvaccination
Measure Description	GMT of the B strain antibody responses at 4 weeks postvaccination in participants who receive ZOSTAVAX™ concomitantly with influenza vaccine and those who receive ZOSTAVAX™ and influenza vaccine nonconcomitantly
Time Frame	4 weeks postvaccination
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.
The analysis was based on the per protocol population defined as participants who had valid results from samples obtained within the prespecified day ranges at Day 1, at Week 4, or at Week 8 postvaccination, and who did not meet any of the protocol violations prespecified in the SAP

Reporting Groups

	Description
Concomitant Group	ZOSTAVAX™ 0.65 mL subcutaneous (SC) injection administered concomitantly with 0.5 mL intramuscular (IM) influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4
Nonconcomitant Group	Influenza vaccine 0.5 mL IM injection administerd with placebo injection on Day 1 and ZOSTAVAX™ 0.65 mL SC injection at Week 4

Measured Values

	Concomitant Group	Nonconcomitant Group
Number of Participants Analyzed [units: participants]	**363**	**363**
GMTs of B Strain Antibody Responses at 4 Weeks Postvaccination [units: titers] Geometric Mean (95% Confidence Interval)	**119.8 (104.8 to 137.1)**	**136.5 (120.5 to 154.7)**

No statistical analysis provided for GMTs of B Strain Antibody Responses at 4 Weeks Postvaccination

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Day 1-28 following each vaccination
Additional Description	Injection-site adverse events (AEs), rashes, oral temperatures (if the subject felt febrile), and other AEs were recorded by the participant on a Vaccination Report Card which was reviewed by the study site personnel at the end of each 28-day follow-up period. 4 participants from each group were lost to follow up & not included in the analysis

Reporting Groups

	Description
Concomitant Group	ZOSTAVAX™ 0.65 mL subcutaneous (SC) injection administered concomitantly with 0.5 mL intramuscular (IM) influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4
Nonconcomitant Group	Influenza vaccine 0.5 mL IM injection administerd with placebo injection on Day 1 and ZOSTAVAX™ 0.65 mL SC injection at Week 4

Serious Adverse Events

	Concomitant Group	Nonconcomitant Group
Total, serious adverse events		
# participants affected / at risk	**6/378 (1.59%)**	**5/376 (1.33%)**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**0/378 (0.00%)**	**1/376 (0.27%)**
Cardiac disorders		

Angina unstable [*1]		
# participants affected / at risk	**0/378 (0.00%)**	**1/376 (0.27%)**
Aortic valve stenosis [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Arrhythmia [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Cardiac failure congestive [*1]		
# participants affected / at risk	**3/378 (0.79%)**	**0/376 (0.00%)**
Myocardial infarction [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Infections and infestations		
Appendicitis [*1]		
# participants affected / at risk	**0/378 (0.00%)**	**1/376 (0.27%)**
Pneumonia [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Injury, poisoning and procedural complications		
Upper limb fracture [*1]		
# participants affected / at risk	**0/378 (0.00%)**	**1/376 (0.27%)**
Musculoskeletal and connective tissue disorders		
Back pain [*1]		
# participants affected / at risk	**0/378 (0.00%)**	**1/376 (0.27%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Basal cell carcinoma [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Nervous system disorders		
Convulsion [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Respiratory, thoracic and mediastinal disorders		
Acute pulmonary oedema [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Chronic obstructive pulmonary disease [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Pulmonary oedema [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**
Respiratory failure [*1]		
# participants affected / at risk	**1/378 (0.26%)**	**0/376 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 9.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Day 1-28 following each vaccination
Additional Description	Injection-site adverse events (AEs), rashes, oral temperatures (if the subject felt febrile), and other AEs were recorded by the participant on a Vaccination Report Card which was reviewed by the study site personnel at the end of each 28-day follow-up period. 4 participants from each group were lost to follow up & not included in the analysis

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Concomitant Group	ZOSTAVAX™ 0.65 mL subcutaneous (SC) injection administered concomitantly with 0.5 mL intramuscular (IM) influenza vaccine injection at separate injection sites on Day 1 and placebo injection at Week 4
Nonconcomitant Group	Influenza vaccine 0.5 mL IM injection administerd with placebo injection on Day 1 and ZOSTAVAX™ 0.65 mL SC injection at Week 4

Other Adverse Events

	Concomitant Group	Nonconcomitant Group
Total, other (not including serious) adverse events		
# participants affected / at risk	**199/378 (52.65%)**	**181/376 (48.14%)**
General disorders		
Injection Site Erythema (Influenza vaccine injection site) † 1		
# participants affected / at risk	**46/378 (12.17%)**	**29/376 (7.71%)**
Injection Site Erythema (Placebo injection site) † 1		
# participants affected / at risk	**11/378 (2.91%)**	**19/376 (5.05%)**
Injection Site Erythema (ZOSTAVAX™ injection site) † 1		
# participants affected / at risk	**125/378 (33.07%)**	**101/376 (26.86%)**
Injection Site Pain (Influenza vaccine injection site) † 1		
# participants affected / at risk	**90/378 (23.81%)**	**86/376 (22.87%)**
Injection Site Pain (Placebo injection site) † 1		
# participants affected / at risk	**16/378 (4.23%)**	**23/376 (6.12%)**
Injection Site Pain (ZOSTAVAX™ injection site) † 1		
# participants affected / at risk	**114/378 (30.16%)**	**107/376 (28.46%)**
Injection Site Swelling (Influenza vaccine injection site) † 1		
# participants affected / at risk	**41/378 (10.85%)**	**31/376 (8.24%)**
Injection Site Swelling (ZOSTAVAX™ injection site) † 1		
# participants affected / at risk	**70/378 (18.52%)**	**94/376 (25.00%)**
Infections and infestations		
*** 1**		

Upper respiratory tract infection		
# participants affected / at risk	**19/378 (5.03%)**	**17/376 (4.52%)**

† Events were collected by systematic assessment
* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA 9.0

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.

Restriction Description: Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications:

Kerzner B, Murray AV, Cheng E, Ifle R, Harvey PR, Tomlinson M, Barben JL, Rarrick K, Stek JE, Chung MO, Schödel FP, Wang WW, Xu J, Chan IS, Silber JL, Schlienger K. Safety and immunogenicity profile of the concomitant administration of ZOSTAVAX and inactivated influenza vaccine in adults aged 50 and older. J Am Geriatr Soc. 2007 Oct;55(10):1499-507.

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Health Authority:	United States: Food and Drug Administration

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