ZOSTAVAX™ in Patients on Chronic/Maintenance Corticosteroids (V211-017) (COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00546819

First received: October 17, 2007
Last updated: February 2, 2016
Last verified: February 2016
History of Changes

Purpose

The purpose of the study was to assess the safety, tolerability, and immunogenicity of ZOSTAVAX™ in patients receiving chronic/maintenance corticosteroids.

Condition	Intervention	Phase
Herpes Zoster	Biological: Zoster Vaccine, Live Biological: Comparator: Placebo	Phase 2

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

Official Title: A Phase IIb Clinical Trial to Evaluate the Safety, Tolerability and Immunogenicity of Zoster Vaccine Live (Oka/Merck) in Patients on Chronic/Maintenance Corticosteroids

Resource links provided by NLM:

MedlinePlus related topics: Shingles Steroids

Drug Information available for: Herpes Zoster Vaccine

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Participants With Serious Adverse Events (SAE) [Time Frame: Up to 182 days postvaccination] [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.

Secondary Outcome Measures:

- Geometric Mean Titer (GMT) of Varicella-Zoster Virus (VZV) Antibodies at 42 Days Postvaccination [Time Frame: 42 days postvaccination] [Designated as safety issue: No]

  The Geometric Mean Titer (GMT) of VZV antibodies in participants' serum samples was assessed by a glycoprotein enzyme-linked immunosorbent assay (gpELISA).

- Geometric Mean Fold Rise (GMFR) of the VZV Antibody Response From Day 1 to Day 42 Postvaccination. [Time Frame: 42 days postvaccination] [Designated as safety issue: No]

  The geometric mean fold rise (GMFR) of the VZV antibodies from Day 1 to Week 6 postvaccination.

Enrollment:	309
Study Start Date:	October 2007
Study Completion Date:	August 2010
Primary Completion Date:	August 2010 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: ZOSTAVAX™ Participants administered ZOSTAVAX™ on Day 1.	Biological: Zoster Vaccine, Live A single dose of 0.65 ml Zoster Vaccine, Live, injected subcutaneously on Day 1 Other Name: V211
Placebo Comparator: Placebo Participants administered Placebo on Day 1.	Biological: Comparator: Placebo A single dose of 0.65 ml Placebo to ZOSTAVAX™ injected subcutaneously on Day 1.

Eligibility

Ages Eligible for Study:	60 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Varicella-history positive, herpes zoster (HZ)-history negative patients
- 60 years of age and older receiving chronic/maintenance systemic corticosteroid therapy at a daily dose of 5 to 20 mg of prednisone or equivalent for at least the 2 weeks immediately prior to enrollment and expected to continue to receive a daily dose of 5 to 20 mg of prednisone or equivalent for the 6-week primary safety follow-up period (dose may vary within this range during the 6-week postvaccination period)
- All females enrolling must be postmenopausal

Exclusion Criteria:

- Patients with a history of hypersensitivity reaction to gelatin or neomycin
- Prior receipt of varicella or zoster vaccine; prior history of herpes zoster
- Immune globulin and/or blood products given within 5 months prior to or expected within the 6-week postvaccination period
- Receipt of any live virus vaccinations within 1 month or receipt of any inactivated vaccinations within 7 days prior to enrollment
- Known immune deficiency that is caused by a medical condition
- Any use in the 8 weeks prior to vaccination or for 6 weeks after vaccination other medications which may suppress the immune system including methotrexate, corticosteroids at a daily dose greater than 20 mg of prednisone or equivalent, agents used to treat cancer, or medications which alter the level of the immune response used to treat arthritis or other illnesses
- Concomitant use of antiviral therapy
- A history of alcohol abuse or recreational drug use

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: NCT00546819

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Russell AF, Parrino J, Fisher CL Jr, Spieler W, Stek JE, Coll KE, Su SC, Xu J, Li X, Schlienger K, Silber JL. Safety, tolerability, and immunogenicity of zoster vaccine in subjects on chronic/maintenance corticosteroids. Vaccine. 2015 Jun 17;33(27):3129-34. doi: 10.1016/j.vaccine.2015.04.090. Epub 2015 May 8.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00546819 History of Changes
Other Study ID Numbers:	V211-017 2006_557
Study First Received:	October 17, 2007
Results First Received:	July 20, 2011
Last Updated:	February 2, 2016
Health Authority:	United States: Food and Drug Administration

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: July 20, 2011

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Prevention
Condition:	Herpes Zoster
Interventions:	Biological: Zoster Vaccine, Live 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 administered ZOSTAVAX™ on Day 1.
Placebo	Participants administered Placebo on Day 1.

Participant Flow: Overall Study

	ZOSTAVAX™	Placebo
STARTED	**207**	**102**
VACCINATED	**206**	**100**
COMPLETED	**199**	**96**
NOT COMPLETED	**8**	**6**
Adverse Event	**2**	**3**
Lost to Follow-up	**2**	**1**
Withdrawal by Subject	**4**	**2**

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 administered ZOSTAVAX™ on Day 1.
Placebo	Participants administered Placebo on Day 1.
Total	Total of all reporting groups

Baseline Measures

	ZOSTAVAX™	Placebo	Total
Number of Participants [units: participants]	**207**	**102**	**309**
Age [units: years] Mean (Standard Deviation)	**69.8 (6.9)**	**69.9 (7.2)**	**69.8 (7.0)**
Gender [units: participants]			
Female	**140**	**80**	**220**
Male	**67**	**22**	**89**

Daily Corticosteroid Dose Stratum [units: Participants]			
5 to 10 mg of prednisone or equivalent	182	88	270
>10 to 20 mg of prednisone or equivalent	25	14	39

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Serious Adverse Events (SAE) [Time Frame: Up to 182 days postvaccination]

Measure Type	Primary
Measure Title	Number of Participants With Serious Adverse Events (SAE)
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	Up to 182 days postvaccination
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 and had any safety follow-up were included in the safety analysis.

Reporting Groups

	Description
ZOSTAVAX™	Participants administered ZOSTAVAX™ on Day 1.
Placebo	Participants administered Placebo on Day 1.

Measured Values

	ZOSTAVAX™	Placebo
Number of Participants Analyzed [units: participants]	**204**	**99**
Number of Participants With Serious Adverse Events (SAE) [units: Participants]	**21**	**11**

No statistical analysis provided for Number of Participants With Serious Adverse Events (SAE)

2. Secondary: Geometric Mean Titer (GMT) of Varicella-Zoster Virus (VZV) Antibodies at 42 Days Postvaccination [Time Frame: 42 days postvaccination]

Measure Type	Secondary
Measure Title	Geometric Mean Titer (GMT) of Varicella-Zoster Virus (VZV) Antibodies at 42 Days Postvaccination
Measure Description	The Geometric Mean Titer (GMT) of VZV antibodies in participants' serum samples was assessed by a glycoprotein enzyme-linked immunosorbent assay (gpELISA).
Time Frame	42 days 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.
Per-protocol population: All vaccinated participants who had serology results and who had no protocol deviations that would interfere with the evaluation of VZV-specific gpELISA antibody response.

Reporting Groups

	Description
ZOSTAVAX™	Participants administered ZOSTAVAX™ on Day 1.
Placebo	Participants administered Placebo on Day 1.

Measured Values

	ZOSTAVAX™	**Placebo**
Number of Participants Analyzed [units: participants]	**167**	**88**
Geometric Mean Titer (GMT) of Varicella-Zoster Virus (VZV) Antibodies at 42 Days Postvaccination [units: gpELISA units/mL] Mean (95% Confidence Interval)	**531.1 (453.3 to 622.1)**	**224.3 (169.8 to 296.2)**

No statistical analysis provided for Geometric Mean Titer (GMT) of Varicella-Zoster Virus (VZV) Antibodies at 42 Days Postvaccination

3. Secondary: Geometric Mean Fold Rise (GMFR) of the VZV Antibody Response From Day 1 to Day 42 Postvaccination. [Time Frame: 42 days postvaccination]

Measure Type	Secondary
Measure Title	Geometric Mean Fold Rise (GMFR) of the VZV Antibody Response From Day 1 to Day 42 Postvaccination.
Measure Description	The geometric mean fold rise (GMFR) of the VZV antibodies from Day 1 to Week 6 postvaccination.
Time Frame	42 days 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.
Per-protocol population: All vaccinated participants who had serology results and who had no protocol deviations that would interfere with the evaluation of VZV-specific gpELISA antibody response.

Reporting Groups

	Description
ZOSTAVAX™	Participants administered ZOSTAVAX™ on Day 1.
Placebo	Participants administered Placebo on Day 1.

Measured Values

	ZOSTAVAX™	Placebo
Number of Participants Analyzed [units: participants]	**167**	**88**
Geometric Mean Fold Rise (GMFR) of the VZV Antibody Response From Day 1 to Day 42 Postvaccination. [units: Ratio] Mean (95% Confidence Interval)	**2.3 (2.0 to 2.7)**	**1.1 (1.0 to 1.2)**

No statistical analysis provided for Geometric Mean Fold Rise (GMFR) of the VZV Antibody Response From Day 1 to Day 42 Postvaccination.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Up to 182 days postvaccination for serious adverse events and 42 days postvaccination for other adverse events.
Additional Description	No text entered.

Reporting Groups

	Description
ZOSTAVAX™	Participants administered ZOSTAVAX™ on Day 1.
Placebo	Participants administered Placebo on Day 1.

Serious Adverse Events

	ZOSTAVAX™	Placebo
Total, serious adverse events		
# participants affected / at risk	**21/204 (10.29%)**	**11/99 (11.11%)**
Cardiac disorders		
Acute myocardial infarction † 1		
# participants affected / at risk	**1/204 (0.49%)**	**0/99 (0.00%)**
# events	**1**	**0**
Cardiac arrest † 1		
# participants affected / at risk	**0/204 (0.00%)**	**1/99 (1.01%)**
# events	**0**	**1**
Hypertensive heart disease † 1		

# participants affected / at risk	0/204 (0.00%)	1/99 (1.01%)
# events	0	1
Endocrine disorders		
Goitre † 1		
# participants affected / at risk	0/204 (0.00%)	1/99 (1.01%)
# events	0	1
Gastrointestinal disorders		
Food poisoning † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
Inguinal hernia, obstructive † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
Large intestine perforation † 1		
# participants affected / at risk	0/204 (0.00%)	1/99 (1.01%)
# events	0	1
Pancreatitis acute † 1		
# participants affected / at risk	0/204 (0.00%)	1/99 (1.01%)
# events	0	1
Upper gastrointestinal haemorrhage † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
General disorders		
Chest pain † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
Infections and infestations		
Cellulitis † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
Cellulitis of male external genital organ † 1		
# participants affected / at risk	0/204 (0.00%)	1/99 (1.01%)
# events	0	1
Gastritis viral † 1		
# participants affected / at risk	0/204 (0.00%)	1/99 (1.01%)
# events	0	1
Gastroenteritis † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
Herpes zoster ophthalmic † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
Kidney infection † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0

Pneumonia † 1		
# participants affected / at risk	**3/204 (1.47%)**	**2/99 (2.02%)**
# events	**3**	**2**
Scrotal abscess † 1		
# participants affected / at risk	**0/204 (0.00%)**	**1/99 (1.01%)**
# events	**0**	**1**
Injury, poisoning and procedural complications		
Comminuted fracture † 1		
# participants affected / at risk	**1/204 (0.49%)**	**0/99 (0.00%)**
# events	**1**	**0**
Hip fracture † 1		
# participants affected / at risk	**0/204 (0.00%)**	**1/99 (1.01%)**
# events	**0**	**1**
Musculoskeletal and connective tissue disorders		
Arthritis † 1		
# participants affected / at risk	**1/204 (0.49%)**	**0/99 (0.00%)**
# events	**1**	**0**
Musculoskeletal pain † 1		
# participants affected / at risk	**1/204 (0.49%)**	**0/99 (0.00%)**
# events	**1**	**0**
Osteoarthritis † 1		
# participants affected / at risk	**0/204 (0.00%)**	**1/99 (1.01%)**
# events	**0**	**1**
Nervous system disorders		
Cerebrovascular accident † 1		
# participants affected / at risk	**1/204 (0.49%)**	**1/99 (1.01%)**
# events	**1**	**1**
Complex regional pain syndrome † 1		
# participants affected / at risk	**1/204 (0.49%)**	**0/99 (0.00%)**
# events	**1**	**0**
Psychiatric disorders		
Bipolar disorder † 1		
# participants affected / at risk	**0/204 (0.00%)**	**1/99 (1.01%)**
# events	**0**	**1**
Renal and urinary disorders		
Renal failure † 1		
# participants affected / at risk	**0/204 (0.00%)**	**1/99 (1.01%)**
# events	**0**	**1**
Respiratory, thoracic and mediastinal disorders		
Chronic obstructive pulmonary disease † 1		
# participants affected / at risk	**7/204 (3.43%)**	**2/99 (2.02%)**
# events	**9**	**2**
Pulmonary embolism † 1		

# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
Pulmonary hypertension † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0
Pulmonary oedema † 1		
# participants affected / at risk	0/204 (0.00%)	1/99 (1.01%)
# events	0	1
Respiratory failure † 1		
# participants affected / at risk	0/204 (0.00%)	1/99 (1.01%)
# events	0	1
Vascular disorders		
Deep vein thrombosis † 1		
# participants affected / at risk	2/204 (0.98%)	0/99 (0.00%)
# events	2	0
Thrombosis † 1		
# participants affected / at risk	1/204 (0.49%)	0/99 (0.00%)
# events	1	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

Other Adverse Events

Hide Other Adverse Events

Time Frame	Up to 182 days postvaccination for serious adverse events and 42 days postvaccination for other adverse events.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
ZOSTAVAX™	Participants administered ZOSTAVAX™ on Day 1.
Placebo	Participants administered Placebo on Day 1.

Other Adverse Events

	ZOSTAVAX™	Placebo
Total, other (not including serious) adverse events		
# participants affected / at risk	43/204 (21.08%)	10/99 (10.10%)
General disorders		

Injection site erythema † 1		
# participants affected / at risk	**36/204 (17.65%)**	**4/99 (4.04%)**
# events	**39**	**4**
Injection site pain † 1		
# participants affected / at risk	**22/204 (10.78%)**	**8/99 (8.08%)**
# events	**23**	**8**
Injection site swelling † 1		
# participants affected / at risk	**23/204 (11.27%)**	**5/99 (5.05%)**
# events	**24**	**5**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA 13.0

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: The SPONSOR must have the opportunity to review all proposed abstracts, manuscripts, or presentations regarding this study 60 days prior to submission for publication/presentation. SPONSOR review can be expedited to meet publication guidelines.

Results Point of Contact:

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

Publications of Results:

Russell AF, Parrino J, Fisher CL Jr, Spieler W, Stek JE, Coll KE, Su SC, Xu J, Li X, Schlienger K, Silber JL. Safety, tolerability, and immunogenicity of zoster vaccine in subjects on chronic/maintenance corticosteroids. Vaccine. 2015 Jun 17;33(27):3129-34. doi: 10.1016/j.vaccine.2015.04.090.

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