Study of Recombinant Modified Process Hepatitis B Vaccine in Older Adults (V232-059)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00440531

First received: February 26, 2007
Last updated: December 30, 2015
Last verified: December 2015
History of Changes

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

Purpose

The purpose of this trial is to determine if there is an improvement in the immune response of older adults over 50 years of age using a modified process hepatitis B vaccine and a currently licensed hepatitis B vaccine (RECOMBIVAX HB™).

Condition	Intervention	Phase
Hepatitis B	Biological: Comparator: RECOMBIVAX HB™ Hepatitis B Vaccine (Recombinant) Biological: Comparator: Modified Process Hepatitis B Vaccine (Experimental) Biological: Comparator: ENGERIX-B™ (currently licensed product)	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 Study in Healthy Adults of the Safety, Tolerability, and Immunogenicity of Recombinant Hepatitis B Vaccine Manufactured With a Modified Process

Resource links provided by NLM:

MedlinePlus related topics: Hepatitis Hepatitis A Hepatitis B

Drug Information available for: Hepatitis B vaccine (recombinant) Recombivax HB Hepatitis A Vaccines

U.S. FDA Resources

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

Primary Outcome Measures:

- The Number of Seroresponders to the Modified Process Hepatitis B Vaccine and RECOMBIVAX HB™ (Currently Licensed Vaccine) [Time Frame: 7 months (1 month after third vaccination)] [Designated as safety issue: No]

  The number of participants as measured by the seroprotection rate (anti-hepatitis B surface antibodies greater than or equal to 10 mIU/mL). Anti-HBs (Antibodies against hepatitis B surface antigen) titers were measured from blood samples taken at Day 1 (prior to the first vaccination) and at Month 7 (1 month after the third vaccination).

Secondary Outcome Measures:

- The Number of Seroresponders to ENGERIX-B™ (Currently Licensed Vaccine) [Time Frame: 7 months (1 month after third vaccination)] [Designated as safety issue: No]

  The number of participants as measured by the seroprotection rate (anti-hepatitis B surface antibodies greater than or equal to 10 mIU/mL). Anti-HBs (Antibodies against hepatitis B surface antigen) titers were measured from blood samples taken at Day 1 (prior to the first vaccination) and at Month 7 (1 month after the third vaccination).

- The Total Number of Participants With One or More Injection-site Adverse Experiences [Time Frame: Days 1-5 After Any Vaccination] [Designated as safety issue: Yes]
- The Total Number of Participants With a Maximum Temperature >=100.0F/37.8C [Time Frame: Day 1-5 After Vaccination] [Designated as safety issue: Yes]
- The Total Number of Participants With Serious Vaccine-Related Clinical Adverse Experiences [Time Frame: During Entire Study Period (from first vaccination until the participant completes or discontinues: up to 7 months)] [Designated as safety issue: Yes]

Enrollment:	540
Study Start Date:	November 2006
Study Completion Date:	November 2007
Primary Completion Date:	November 2007 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: 1 RECOMBIVAX HB™	Biological: Comparator: RECOMBIVAX HB™ Hepatitis B Vaccine (Recombinant) RECOMBIVAX HB™ (currently licensed product) given IM (Intramuscular) in 3 doses of 10 mcg (micrograms)/1.0 mL each over 6 months.
Experimental: 2 Modified Process Hepatitis B Vaccine	Biological: Comparator: Modified Process Hepatitis B Vaccine (Experimental) Modified Process Hepatitis B Vaccine (Experimental) given IM (Intramuscular) in 3 doses of 10 mcg (micrograms)/1.0 mL each over 6 months.
Active Comparator: 3 ENGERIX-B™	Biological: Comparator: ENGERIX-B™ (currently licensed product) ENGERIX-B™ given IM (Intramuscular) in 3 doses of 20 mcg (micrograms)/1.0 mL each over 6 months.

Eligibility

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

Criteria

Inclusion Criteria:

- Healthy male and female older adults greater than or equal to 50 years of age

Exclusion Criteria:

- Any adult with a history of previous hepatitis B infection
- A history of vaccination with any hepatitis B vaccine
- Recent (<72 hours) history of febrile illness (oral temperature =37.8ºC/=100.0ºF)
- Known or suspected hypersensitivity to any component of RECOMBIVAX HB™ or ENGERIX-B™ (e.g., aluminum, yeast)
- Recent administration (within 3 months prior to first injection with the study vaccine) of hepatitis B immune globulin (HBIG), serum immune globulin, or any other blood-derived product

Receipt of licensed inactivated vaccines within 14 days prior to first injection with the study vaccine

- Receipt of licensed live virus vaccines within the 30 days prior to injection with the study vaccine
- Receipt of investigational drugs or other investigational vaccines within 3 months prior to first injection with the study vaccine
- Known or suspected impairment of immunologic function or recent use of immunomodulatory medications (e.g., systemic corticosteroids). Does not include topical and inhaled steroids
- Pregnant women, nursing mothers, and women planning to become pregnant within the study period
- Any condition that, in the opinion of the investigator, might interfere with the evaluation of the study objectives

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: NCT00440531

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

No publications provided by Merck Sharp & Dohme Corp.

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

Gilbert CL, Klopfer SO, Martin JC, Schödel FP, Bhuyan PK. Safety and immunogenicity of a modified process hepatitis B vaccine in healthy adults ≥50 years. Hum Vaccin. 2011 Dec;7(12):1336-42. doi: 10.4161/hv.7.12.18333. Epub 2011 Dec 1.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00440531 History of Changes
Other Study ID Numbers:	V232-059 2007_516
Study First Received:	February 26, 2007
Results First Received:	November 11, 2008
Last Updated:	December 30, 2015
Health Authority:	Canada: Health Canada

Additional relevant MeSH terms:

Hepatitis	Hepadnaviridae Infections
Hepatitis A	Hepatitis, Viral, Human
Hepatitis B	Liver Diseases
DNA Virus Infections	Picornaviridae Infections
Digestive System Diseases	RNA Virus Infections
Enterovirus Infections	Virus Diseases

ClinicalTrials.gov processed this record on April 07, 2016

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First received: February 26, 2007
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History of Changes

Results First Received: November 11, 2008

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:	Hepatitis B
Interventions:	Biological: Comparator: RECOMBIVAX HB™ Hepatitis B Vaccine (Recombinant) Biological: Comparator: Modified Process Hepatitis B Vaccine (Experimental) Biological: Comparator: ENGERIX-B™ (currently licensed product)

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
27-Nov-2006 (First Participant Enrolled in Study) to 26-Nov-2007 (Last Participant had their Last Visit). This study was conducted at 22 sites: 10 in Canada, 2 in Denmark, 5 in Sweden, and 5 in the United Kingdom.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
In the Modified Process group, 2 participants were randomized but not vaccinated: 1 participant withdrew consent, and 1 participant had an SAE (Serious Adverse Experience) of hypertension prior to vaccination.

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 10 µg (micrograms)
RECOMBIVAX-HB™	RECOMBIVAX-HB™, 10 µg (micrograms)
ENGERIX-B™	ENGERIX-B™, 20 µg (micrograms)

Participant Flow: Overall Study

	Modified Process Hepatitis B Vaccine	RECOMBIVAX-HB™	ENGERIX-B™
STARTED	**185**	**183**	**172**
Vaccination 1	**183**	**183**	**172**
Vaccination 2	**181**	**182**	**171**
Vaccination 3	**176**	**178**	**166**
COMPLETED	**175**	**178**	**165**
NOT COMPLETED	**10**	**5**	**7**
Adverse Event	**1**	**0**	**2**
Withdrawal by Subject	**2**	**0**	**0**
Protocol Violation	**1**	**2**	**0**
Lost to Follow-up	**4**	**3**	**5**
see pre-assignment details	**2**	**0**	**0**

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
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 10 µg (micrograms)
RECOMBIVAX-HB™	RECOMBIVAX-HB™, 10 µg (micrograms)
ENGERIX-B™	ENGERIX-B™, 20 µg (micrograms)
Total	Total of all reporting groups

Baseline Measures

	Modified Process Hepatitis B Vaccine	RECOMBIVAX-HB™	ENGERIX-B™	Total
Number of Participants				

[units: participants]	**183**	**183**	**172**	**538**
Age [units: years] Mean (Standard Deviation)	**60.3 (7.9)**	**60.4 (7.6)**	**59.8 (6.5)**	**60.2 (7.4)**
Gender [units: participants]				
Female	**93**	**94**	**73**	**260**
Male	**90**	**89**	**99**	**278**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Number of Seroresponders to the Modified Process Hepatitis B Vaccine and RECOMBIVAX HB™ (Currently Licensed Vaccine) [Time Frame: 7 months (1 month after third vaccination)]

Measure Type	Primary
Measure Title	The Number of Seroresponders to the Modified Process Hepatitis B Vaccine and RECOMBIVAX HB™ (Currently Licensed Vaccine)
Measure Description	The number of participants as measured by the seroprotection rate (anti-hepatitis B surface antibodies greater than or equal to 10 mIU/mL). Anti-HBs (Antibodies against hepatitis B surface antigen) titers were measured from blood samples taken at Day 1 (prior to the first vaccination) and at Month 7 (1 month after the third vaccination).
Time Frame	7 months (1 month after third vaccination)
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. The Per-protocol Population is defined as the participants that were able to complete the study as defined by the protocol.

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 10 µg (micrograms)
RECOMBIVAX-HB™	RECOMBIVAX-HB™, 10 µg (micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	**RECOMBIVAX-HB™**
Number of Participants Analyzed [units: participants]	**152**	**147**
The Number of Seroresponders to the Modified Process Hepatitis B Vaccine and RECOMBIVAX HB™ (Currently Licensed Vaccine) [units: Participants]	**115**	**100**

Statistical Analysis 1 for The Number of Seroresponders to the Modified Process Hepatitis B Vaccine and RECOMBIVAX HB™ (Currently Licensed Vaccine)

Groups [1]	Modified Process Hepatitis B Vaccine
single-group percentage [2]	75.70
95% Confidence Interval	68 to 82.20

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No hypothesis is being tested. The purpose of the primary analysis is to estimate the seroprotection rate (percentage of subjects with anti-HBs >=10mIU/mL) in each group at 1 month post vaccination 3, among subjects who were seronegative at baseline.
[2]	Other relevant estimation information:
	No text entered.

Statistical Analysis 2 for The Number of Seroresponders to the Modified Process Hepatitis B Vaccine and RECOMBIVAX HB™ (Currently Licensed Vaccine)

Groups [1]	RECOMBIVAX-HB™
single-group percentage [2]	68
95% Confidence Interval	59.80 to 75.50

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No hypothesis is being tested. The purpose of the primary analysis is to estimate the seroprotection rate (percentage of subjects with anti-HBs >=10mIU/mL) in each group at 1 month post vaccination 3, among subjects who were seronegative at baseline.
[2]	Other relevant estimation information:
	No text entered.

2. Secondary: The Number of Seroresponders to ENGERIX-B™ (Currently Licensed Vaccine) [Time Frame: 7 months (1 month after third vaccination)]

Measure Type	Secondary
Measure Title	The Number of Seroresponders to ENGERIX-B™ (Currently Licensed Vaccine)
Measure Description	The number of participants as measured by the seroprotection rate (anti-hepatitis B surface antibodies greater than or equal to 10 mIU/mL). Anti-HBs (Antibodies against hepatitis B surface antigen) titers were measured from blood samples taken at Day 1 (prior to the first vaccination) and at Month 7 (1 month after the third vaccination).
Time Frame	7 months (1 month after third vaccination)
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. The Per-protocol Population is defined as the participants that were able to complete the study as defined by the protocol.

Reporting Groups

	Description

ENGERIX-B™	ENGERIX-B™, 20 µg (micrograms)

Measured Values

	ENGERIX-B™
Number of Participants Analyzed [units: participants]	**144**
The Number of Seroresponders to ENGERIX-B™ (Currently Licensed Vaccine) [units: Participants]	**121**

Statistical Analysis 1 for The Number of Seroresponders to ENGERIX-B™ (Currently Licensed Vaccine)

Groups [1]	ENGERIX-B™
Single-Group Percentage [2]	84
95% Confidence Interval	77 to 89.60

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No hypothesis is being tested. The purpose of the secondary analysis is to estimate the seroprotection rate (percentage of subjects with anti-HBs >=10mIU/mL) for ENGERIX-B™ at 1 month post vaccination 3, among subjects who were seronegative at baseline.
[2]	Other relevant estimation information:
	No text entered.

3. Secondary: The Total Number of Participants With One or More Injection-site Adverse Experiences [Time Frame: Days 1-5 After Any Vaccination]

Measure Type	Secondary
Measure Title	The Total Number of Participants With One or More Injection-site Adverse Experiences
Measure Description	No text entered.
Time Frame	Days 1-5 After Any 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.
Safety Analysis Set – defined as all participants who received at least one injection of vaccine and who had a safety follow-up.

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 10 µg (micrograms)
RECOMBIVAX-HB™	RECOMBIVAX-HB™, 10 µg (micrograms)
ENGERIX-B™	

	ENGERIX-B™, 20 µg (micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	RECOMBIVAX-HB™	ENGERIX-B™
Number of Participants Analyzed [units: participants]	**182**	**183**	**171**
The Total Number of Participants With One or More Injection-site Adverse Experiences [units: Participants]	**103**	**115**	**107**

No statistical analysis provided for The Total Number of Participants With One or More Injection-site Adverse Experiences

4. Secondary: The Total Number of Participants With a Maximum Temperature >=100.0F/37.8C [Time Frame: Day 1-5 After Vaccination]

Measure Type	Secondary
Measure Title	The Total Number of Participants With a Maximum Temperature >=100.0F/37.8C
Measure Description	No text entered.
Time Frame	Day 1-5 After 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.
Safety Analysis Set - defined as all participants who received at least one injection of vaccine and who had a safety follow-up.

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 10 µg (micrograms)
RECOMBIVAX-HB™	RECOMBIVAX-HB™, 10 µg (micrograms)
ENGERIX-B™	ENGERIX-B™, 20 µg (micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	RECOMBIVAX-HB™	ENGERIX-B™
Number of Participants Analyzed [units: participants]	**182**	**183**	**171**
The Total Number of Participants With a Maximum Temperature >=100.0F/37.8C [units: Participants]	**2**	**3**	**3**

No statistical analysis provided for The Total Number of Participants With a Maximum Temperature >=100.0F/37.8C

5. Secondary: The Total Number of Participants With Serious Vaccine-Related Clinical Adverse Experiences [Time Frame: During Entire Study Period (from first vaccination until the participant completes or discontinues: up to 7 months)]

Measure Type	Secondary
Measure Title	The Total Number of Participants With Serious Vaccine-Related Clinical Adverse Experiences
Measure Description	No text entered.
Time Frame	During Entire Study Period (from first vaccination until the participant completes or discontinues: up to 7 months)
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.
Safety Analysis Set – defined as all participants who received at least one injection of vaccine and who had a safety follow-up.

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 10 µg (micrograms)
RECOMBIVAX-HB™	RECOMBIVAX-HB™, 10 µg (micrograms)
ENGERIX-B™	ENGERIX-B™, 20 µg (micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	**RECOMBIVAX-HB™**	**ENGERIX-B™**
Number of Participants Analyzed [units: participants]	**182**	**183**	**171**
The Total Number of Participants With Serious Vaccine-Related Clinical Adverse Experiences [units: Participants]	**0**	**0**	**0**

No statistical analysis provided for The Total Number of Participants With Serious Vaccine-Related Clinical Adverse Experiences

Serious Adverse Events

Hide Serious Adverse Events

No Serious Adverse Events Entered.

Other Adverse Events

Hide Other Adverse Events

No Other Adverse Events Entered.

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, Clinical and Quantitative Sciences
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372

No publications provided by Merck Sharp & Dohme Corp.

Publications automatically indexed to this study:

Gilbert CL, Klopfer SO, Martin JC, Schödel FP, Bhuyan PK. Safety and immunogenicity of a modified process hepatitis B vaccine in healthy adults ≥50 years. Hum Vaccin. 2011 Dec;7(12):1336-42. doi: 10.4161/hv.7.12.18333. Epub 2011 Dec 1.

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Health Authority:	Canada: Health Canada

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For Patients and Families | For Researchers | For Study Record Managers