Hepatitis B Vaccine Predialysis/Dialysis Study (V232-060)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00440297

First received: February 26, 2007
Last updated: October 29, 2015
Last verified: October 2015
History of Changes

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

Purpose

To describe the immunogenicity and safety of modified process hepatitis B vaccine administered to renal predialysis and dialysis patients

Condition	Intervention	Phase
Hepatitis B Virus Infection	Biological: Comparator: modified process hepatitis B vaccine Biological: Comparator: ENGERIX-B™	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Prevention

Official Title: A Study in Renal Predialysis and Dialysis Patients 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 A Vaccines

U.S. FDA Resources

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

Primary Outcome Measures:

- The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 7 [Time Frame: 7 months (1 month after the third dose)] [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 dose) and at Month 7 (1 month after the third dose).

- The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 9 [Time Frame: 9 months (1 month after the fourth dose)] [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 dose) and at Month 9 (1 month after the fourth dose).

- The Total Number of Participants With One or More Injection-Site Adverse Experiences [Time Frame: Days 1-15 After Any Vaccination] [Designated as safety issue: Yes]
- The Total Number of Participants With a Maximum Temperature >= 100.0F / 37.8C [Time Frame: Days 1-5 After Any Vaccination] [Designated as safety issue: Yes]
- The Total Number of Participants With Serious Vaccine-Related Clinical Adverse Experiences [Time Frame: 0-9 months (recorded from first dose until the participant completes or discontinues the study)] [Designated as safety issue: Yes]

  Participants with adverse experiences considered possibly, probably, or definitely related to study vaccines and considered serious (death, persistent disability, life threatening, hospitalization, birth defects, cancer, or overdose).

Enrollment:	277
Study Start Date:	December 2006
Study Completion Date:	May 2008
Primary Completion Date:	May 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Modified process hepatitis B vaccine Modified process hepatitis B vaccine 40 ug/1.0 mL injection in a 4 dose regimen at months 0, 1, 6, and 8. Duration of treatment is 9 months.	Biological: Comparator: modified process hepatitis B vaccine Modified process hepatitis B vaccine 40 ug/1.0 mL injection in a 4 dose regimen at months 0, 1, 6, and 8. Duration of treatment is 9 months.
Active Comparator: ENGERIX-B™2 ENGERIX-B™ two 20 ug/1.0 mL injections in a 4 dose regimen at months 0, 1, 6, and 8. Duration of treatment is 9 months.	Biological: Comparator: ENGERIX-B™ ENGERIX-B™ two 20 ug/1.0 mL injections in a 4 dose regimen at months 0, 1, 6, and 8. Duration of treatment is 9 months.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Male and female subjects at least 18 years of age
- Laboratory confirmed negative serology result to HbsAg (hepatitis b virus), anti-HBs (antibody to hepatitis B surface antigen), and anti HBc (antibody to hepatitis B core antigen) within 6 weeks of the initial dose of study vaccine
- Patient on renal dialysis or a pre-dialysis patient with a creatinine clearance of <=30 ml/min

Exclusion Criteria:

- Previous hepatitis B infection, vaccination with any hepatitis B vaccine
- Recent febrile illness; hypersensitivity to any component of licensed hepatitis B vaccines
- Recent administration of immune globulin, licensed inactivated vaccine within 14 days or licensed live vaccine within 30 days prior to receipt of first study vaccine
- Receipt of investigational drugs or investigational vaccines within 3 months prior

- Impairment of immunologic function
- Recent use of systemic immunomodulatory medications
- Pregnant women, nursing mothers or women planning to become pregnant

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: NCT00440297

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Publications:

Gilbert CL, Stek JE, Villa G, Klopfer SO, Martin JC, Schödel FP, Bhuyan PK. Safety and immunogenicity of a recombinant hepatitis B vaccine manufactured by a modified process in renal pre-dialysis and dialysis patients. Vaccine. 2014 Nov 12;32(48):6521-6. doi: 10.1016/j.vaccine.2014.09.015. Epub 2014 Sep 22.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00440297 History of Changes
Other Study ID Numbers:	V232-060 2007_515
Study First Received:	February 26, 2007
Results First Received:	March 24, 2009
Last Updated:	October 29, 2015
Health Authority:	Canada: Health Canada

Keywords provided by Merck Sharp & Dohme Corp.:
hepatitis B virus

Additional relevant MeSH terms:

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

ClinicalTrials.gov processed this record on April 20, 2016

TO TOP

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

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

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First received: February 26, 2007
Last updated: October 29, 2015
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History of Changes

Results First Received: March 24, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Prevention
Condition:	Hepatitis B Virus Infection
Interventions:	Biological: Comparator: modified process hepatitis B vaccine Biological: Comparator: ENGERIX-B™

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

22-Dec-2006 (First Patient Enrolled in Study) to 05-May-2008 (Last Participant had their Last Visit). This study was conducted at 23 sites: 7 in Canada, 8 in the United Kingdom, 5 in Italy, and 3 in Spain. In the Modified Process group, one participant was randomized by mistake, and therefore was not vaccinated.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment

A screening serum sample was obtained prior to study entry and assayed for hepatitis B serologic markers. Only patients that were seronegative were considered for enrollment.

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)

Participant Flow: Overall Study

	Modified Process Hepatitis B Vaccine	ENGERIX-B™
STARTED	**139**	**138**
Vaccination Visit 1	**138**	**138**
Vaccination Visit 2	**136**	**134**
Vaccination Visit 3	**124**	**125**
Vaccination Visit 4	**116**	**122**
COMPLETED	**116**	**120**
NOT COMPLETED	**23**	**18**
Adverse Event	**8**	**5**
Lost to Follow-up	**1**	**0**
Physician Decision	**1**	**0**
Protocol Violation	**11**	**7**
Withdrawal by Subject	**1**	**6**
Randomized by mistake	**1**	**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.
All vaccinated participants

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)
Total	Total of all reporting groups

Baseline Measures

	Modified Process Hepatitis B Vaccine	ENGERIX-B™	Total
Number of Participants [units: participants]	**138**	**138**	**276**

Age [units: years] Mean (Full Range)	**69.7 (20 to 91)**	**69.2 (30 to 90)**	**69.5 (20 to 91)**
Age [units: Years] Mean (Standard Deviation)	**69.7 (13.4)**	**69.2 (12.7)**	**69.5 (13.0)**
Gender [units: participants]			
Female	**53**	**56**	**109**
Male	**85**	**82**	**167**

Outcome Measures

Hide All Outcome Measures

1. Primary: The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 7 [Time Frame: 7 months (1 month after the third dose)]

Measure Type	Primary
Measure Title	The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 7
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 dose) and at Month 7 (1 month after the third dose).
Time Frame	7 months (1 month after the third dose)
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, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	**ENGERIX-B™**
Number of Participants Analyzed [units: participants]	**101**	**111**
The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and		

ENGERIX-B™ (Currently Licensed Vaccine) at Month 7 [units: Participants]	**49**	**64**

Statistical Analysis 1 for The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 7

Groups [1]	Modified Process Hepatitis B Vaccine
Percentage of Seroprotected Participants [2]	48.5
95% Confidence Interval	38.4 to 58.7

[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 after the third dose among subjects who were seronegative at baseline
[2]	Other relevant estimation information:
	Exact binomial confidence interval.

Statistical Analysis 2 for The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 7

Groups [1]	ENGERIX-B™
Percentage of Seroprotected Participants [2]	57.7
95% Confidence Interval	47.9 to 67.0

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Exact binomial confidence interval.

2. Primary: The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 9 [Time Frame: 9 months (1 month after the fourth dose)]

Measure Type	Primary
Measure Title	The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 9
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 dose) and at Month 9 (1 month after the fourth dose).
Time Frame	9 months (1 month after the fourth dose)
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, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	ENGERIX-B™
Number of Participants Analyzed [units: participants]	**99**	**104**
The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 9 [units: Participants]	**66**	**72**

Statistical Analysis 1 for The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 9

Groups [1]	Modified Process Hepatitis B Vaccine
Percentage of Seroprotected Participants [2]	66.7
95% Confidence Interval	56.5 to 75.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Exact binomial confidence interval

Statistical Analysis 2 for The Number of Seroprotected Participants to the Modified Process Hepatitis B Vaccine and ENGERIX-B™ (Currently Licensed Vaccine) at Month 9

Groups [1]	ENGERIX-B™
Percentage of Seroprotected Participants [2]	69.2
95% Confidence Interval	59.4 to 77.9

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	No text entered.
[2]	Other relevant estimation information:
	Exact binomial confidence interval

3. Primary: The Total Number of Participants With One or More Injection-Site Adverse Experiences [Time Frame: Days 1-15 After Any Vaccination]

Measure Type	Primary
Measure Title	The Total Number of Participants With One or More Injection-Site Adverse Experiences
Measure Description	No text entered.
Time Frame	Days 1-15 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: The Safety Analysis Set is defined as all participants who receive 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, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	**ENGERIX-B™**
Number of Participants Analyzed [units: participants]	**138**	**135**
The Total Number of Participants With One or More Injection-Site Adverse Experiences [units: Participants]	**43**	**48**

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

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

Measure Type	Primary
Measure Title	The Total Number of Participants With a Maximum Temperature >= 100.0F / 37.8C
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: The Safety Analysis Set is defined as all participants who receive 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, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	ENGERIX-B™
Number of Participants Analyzed [units: participants]	**138**	**135**
The Total Number of Participants With a Maximum Temperature >= 100.0F / 37.8C [units: Participants]	**5**	**6**

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

5. Primary: The Total Number of Participants With Serious Vaccine-Related Clinical Adverse Experiences [Time Frame: 0-9 months (recorded from first dose until the participant completes or discontinues the study)]

Measure Type	Primary
Measure Title	The Total Number of Participants With Serious Vaccine-Related Clinical Adverse Experiences
Measure Description	Participants with adverse experiences considered possibly, probably, or definitely related to study vaccines and considered serious (death, persistent disability, life threatening, hospitalization, birth defects, cancer, or overdose).
Time Frame	0-9 months (recorded from first dose until the participant completes or discontinues the study)
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: The Safety Analysis Set is defined as all participants who receive 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, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)

Measured Values

	Modified Process Hepatitis B Vaccine	ENGERIX-B™
Number of Participants Analyzed [units: participants]	**138**	**135**
The Total Number of Participants With Serious Vaccine-Related Clinical Adverse		

Experiences [units: Participants]	**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

Time Frame	All adverse events: Days 1-15 after any vaccination; Deaths and vaccine-related serious adverse events: up to 9 months
Additional Description	No text entered.

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)

Serious Adverse Events

	Modified Process Hepatitis B Vaccine	**ENGERIX-B™**
Total, serious adverse events		
# participants affected	**11**	**11**
Blood and lymphatic system disorders		
Anaemia * 1		
# participants affected / at risk	**1/138 (0.72%)**	**1/135 (0.74%)**
Cardiac disorders		
Myocardial Infarction * 1		
# participants affected / at risk	**4/138 (2.90%)**	**2/135 (1.48%)**
Cardiac failure congestive * 1		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
Cardiac arrest * 1		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
Cardio-respiratory arrest * 1		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
Gastrointestinal disorders		
Pancreatitis acute * 1		
# participants affected / at risk	**1/138 (0.72%)**	**0/135 (0.00%)**
Gastric ulcer * 1		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
General disorders		
* 1		

Liver function test abnormal		
# participants affected / at risk	**1/138 (0.72%)**	**0/135 (0.00%)**
Hepatobiliary disorders		
Hepatitis [*1]		
# participants affected / at risk	**1/138 (0.72%)**	**0/135 (0.00%)**
Infections and infestations		
Pneumonia [*1]		
# participants affected / at risk	**2/138 (1.45%)**	**0/135 (0.00%)**
Sepsis [*1]		
# participants affected / at risk	**0/138 (0.00%)**	**2/135 (1.48%)**
Injury, poisoning and procedural complications		
Hip fracture [*1]		
# participants affected / at risk	**1/138 (0.72%)**	**0/135 (0.00%)**
Renal haematoma [*1]		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
Arteriovenous fistula site complication [*1]		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
Metabolism and nutrition disorders		
Hypoglycaemia [*1]		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
Musculoskeletal and connective tissue disorders		
Muscular weakness [*1]		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Renal neoplasm [*1]		
# participants affected / at risk	**1/138 (0.72%)**	**0/135 (0.00%)**
Metastases to liver [*1]		
# participants affected / at risk	**1/138 (0.72%)**	**0/135 (0.00%)**
Nervous system disorders		
Cerebral ischaemia [*1]		
# participants affected / at risk	**1/138 (0.72%)**	**0/135 (0.00%)**
Renal and urinary disorders		
Renal failure [*1]		
# participants affected / at risk	**1/138 (0.72%)**	**2/135 (1.48%)**
Renal failure chronic [*1]		
# participants affected / at risk	**0/138 (0.00%)**	**1/135 (0.74%)**
Respiratory, thoracic and mediastinal disorders		
Acute pulmonary oedema [*1]		
# participants affected / at risk	**1/138 (0.72%)**	**0/135 (0.00%)**
Emphysema [*1]		

# participants affected / at risk	1/138 (0.72%)	0/135 (0.00%)
Pulmonary embolism * 1		
# participants affected / at risk	1/138 (0.72%)	0/135 (0.00%)
Chronic obstructive pulmonary disease * 1		
# participants affected / at risk	0/138 (0.00%)	1/135 (0.74%)
Vascular disorders		
Circulatory collapse * 1		
# participants affected / at risk	0/138 (0.00%)	1/135 (0.74%)

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	All adverse events: Days 1-15 after any vaccination; Deaths and vaccine-related serious adverse events: up to 9 months
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	1%

Reporting Groups

	Description
Modified Process Hepatitis B Vaccine	Modified Process Hepatitis B Vaccine, 40 µg(micrograms)
ENGERIX-B™	ENGERIX-B™, 2 x 20 µg(micrograms)

Other Adverse Events

	Modified Process Hepatitis B Vaccine	ENGERIX-B™
Total, other (not including serious) adverse events		
# participants affected	56	73
Gastrointestinal disorders		
Constipation † 1		
# participants affected / at risk	2/138 (1.45%)	1/135 (0.74%)
Diarrhea † 1		
# participants affected / at risk	5/138 (3.62%)	6/135 (4.44%)
Nausea † 1		
# participants affected / at risk	3/138 (2.17%)	2/135 (1.48%)
Vomiting † 1		
# participants affected / at risk	2/138 (1.45%)	1/135 (0.74%)

General disorders		
Asthenia † 1		
# participants affected / at risk	**1/138 (0.72%)**	**2/135 (1.48%)**
Fatigue † 1		
# participants affected / at risk	**4/138 (2.90%)**	**1/135 (0.74%)**
Edema peripheral † 1		
# participants affected / at risk	**1/138 (0.72%)**	**3/135 (2.22%)**
Pyrexia † 1		
# participants affected / at risk	**4/138 (2.90%)**	**6/135 (4.44%)**
Injection site Erythema † 1		
# participants affected / at risk	**7/138 (5.07%)**	**19/135 (14.07%)**
Injection site Edema † 1		
# participants affected / at risk	**1/138 (0.72%)**	**2/135 (1.48%)**
Injection site Pain † 1		
# participants affected / at risk	**32/138 (23.19%)**	**39/135 (28.89%)**
Injection site Swelling † 1		
# participants affected / at risk	**12/138 (8.70%)**	**14/135 (10.37%)**
Infections and infestations		
Cystitis † 1		
# participants affected / at risk	**2/138 (1.45%)**	**0/135 (0.00%)**
Lower respiratory tract infection † 1		
# participants affected / at risk	**0/138 (0.00%)**	**2/135 (1.48%)**
Nasopharyngitis † 1		
# participants affected / at risk	**2/138 (1.45%)**	**3/135 (2.22%)**
Urinary tract infection † 1		
# participants affected / at risk	**0/138 (0.00%)**	**3/135 (2.22%)**
Musculoskeletal and connective tissue disorders		
Athralgia † 1		
# participants affected / at risk	**3/138 (2.17%)**	**4/135 (2.96%)**
Muscle spasms † 1		
# participants affected / at risk	**2/138 (1.45%)**	**1/135 (0.74%)**
Pain in extremity † 1		
# participants affected / at risk	**2/138 (1.45%)**	**1/135 (0.74%)**
Nervous system disorders		
Dizziness † 1		
# participants affected / at risk	**4/138 (2.90%)**	**5/135 (3.70%)**
Headache † 1		
# participants affected / at risk	**8/138 (5.80%)**	**8/135 (5.93%)**
Psychiatric disorders		

Insomnia † 1		
# participants affected / at risk	**0/138 (0.00%)**	**4/135 (2.96%)**
Respiratory, thoracic and mediastinal disorders		
Cough † 1		
# participants affected / at risk	**2/138 (1.45%)**	**2/135 (1.48%)**
Pharyngolaryngeal pain † 1		
# participants affected / at risk	**2/138 (1.45%)**	**0/135 (0.00%)**
Rhinorrhea † 1		
# participants affected / at risk	**0/138 (0.00%)**	**2/135 (1.48%)**
Skin and subcutaneous tissue disorders		
Pruritis † 1		
# participants affected / at risk	**1/138 (0.72%)**	**2/135 (1.48%)**

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

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:

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Publications of Results:

Gilbert CL, Stek JE, Villa G, Klopfer SO, Martin JC, Schödel FP, Bhuyan PK. Safety and immunogenicity of a recombinant hepatitis B vaccine manufactured by a modified process in renal pre-dialysis and dialysis patients. Vaccine. 2014 Nov 12;32(48):6521-6. doi: 10.1016/j.vaccine.2014.09.015. Epub 2014 Sep 22.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00440297 History of Changes
Other Study ID Numbers:	V232-060 2007_515 (Other Identifier: Merck Registration Number)
Study First Received:	February 26, 2007
Results First Received:	March 24, 2009
Last Updated:	October 29, 2015
Health Authority:	Canada: Health Canada

TO TOP

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

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