

# Post-Marketing Observational Surveillance Study to Evaluate the Incidence of New-Onset Immune-Mediated Diseases, Herpes Zoster, and Anaphylaxis in Adults 18 Years of Age and Older Who Receive HEPLISAV B® Compared with Another Hepatitis B Vaccine (DV2-HBV-26)

**First published:** 03/02/2023

**Last updated:** 23/04/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS50455

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### Study ID

50456

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### DARWIN EU® study

No

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## Study countries

 United States

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## Study description

The primary objective of this post-marketing observational surveillance study was to describe and compare the incidence of new-onset immune-mediated diseases, herpes zoster, and anaphylaxis in recipients of HEPLISAV B with recipients of another hepatitis B vaccine.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### Dynavax Technologies

**First published:** 01/02/2024

**Last updated:** 01/02/2024

Institution

Multiple centres: 15 centres are involved in the study

## Contact details

**Study institution contact**

Samy Chabri samy.chabri@propharmagroup.com

Study contact

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**Primary lead investigator**

Robert S. Janssen

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Actual: 02/04/2018

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**Study start date**

Actual: 07/08/2018

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**Data analysis start date**

Actual: 30/11/2020

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**Date of final study report**

Actual: 23/02/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Dynavax Technologies Corporation

## Study protocol

[DV2-HBV-26-protocol-amend-22May18.pdf](#) (1.5 MB)

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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### **Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

#### **Study topic:**

Disease /health condition

Human medicinal product

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#### **Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of this post-marketing observational surveillance study was to describe and compare the incidence of new-onset immune-mediated diseases, herpes zoster, and anaphylaxis in recipients of HEPLISAV B with recipients of another hepatitis B vaccine.

## Study Design

**Non-interventional study design**

Cluster design

Cohort

Other

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**Non-interventional study design, other**

Non-randomized cluster design

## Study drug and medical condition

**Medicinal product name**

**Study drug International non-proprietary name (INN) or common name**  
HEPATITIS B SURFACE ANTIGEN

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**Anatomical Therapeutic Chemical (ATC) code**

(J07BC01) hepatitis B, purified antigen  
hepatitis B, purified antigen

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**Medical condition to be studied**

Hepatitis B virus test  
Vasculitis  
Alopecia areata  
Graves' disease  
Bell's palsy  
Erythema nodosum  
Giant cell arteritis  
Guillain-Barre syndrome  
Lichen planus  
Polyarteritis nodosa  
Polymyalgia rheumatica  
Rheumatoid arthritis  
Scleroderma  
Systemic lupus erythematosus  
Takayasu's arteritis  
Colitis ulcerative  
Tolosa-Hunt syndrome  
Vitiligo

**Population studied**

## **Short description of the study population**

The study population included patients aged 18 years or older received hepatitis B vaccination registered in the KPSC research data warehouse.

Inclusion criteria:

1. Received at least 1 dose of hepatitis B vaccine (either HEPLISAV-B in HEPLISAV-B arm, or non-dialysis formulation hepatitis B comparator vaccine in comparator arm) at KPSC during study vaccination period
2. Enrolled as a KPSC member at time of hepatitis B vaccination during the study vaccination period
3. Age 18 years or older at time of hepatitis B vaccination during study vaccination period
4. Received hepatitis B vaccine at KPSC family practice or internal medicine departments, or in urgent care or nurse clinics affiliated with those departments

Exclusion criteria:

1. Received peritoneal dialysis or chronic hemodialysis (more than 9 dialysis sessions in the past 3 months) prior to index hepatitis B vaccination
  2. Received all doses of their hepatitis B vaccine series in KPSC departments other than family practice or internal medicine or their affiliated departments as described above
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## **Age groups**

- Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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## Special population of interest

Immunocompromised

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## Estimated number of subjects

69625

# Study design details

## Outcomes

The outcome of interest was the incidence of selected new-onset immune-mediated diseases, herpes zoster, and anaphylaxis events following the index dose of hepatitis B vaccine. Please see relevant medical condition section 7.0 to have a list of new-onset immune-mediated diseases of interest in this study.

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## Data analysis plan

Baseline demographic and medical factors compared using standardized difference scores; Poisson regression employing inverse probability of treatment weighting (IPTW) for the analysis of immune-mediated diseases, herpes zoster, and anaphylaxis events, where there was at least 80% power to detect a relative risk of 5 for anaphylaxis or at least 80% power to detect a relative risk of 3 for herpes zoster and immune-mediated diseases for a 5% two-sided alpha level and without multiplicity consideration.

## Data management

## ENCePP Seal

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The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### **Data source(s), other**

KPSC Research Data Warehouse

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### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Disease registry](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### **Data sources (types), other**

Prospective patient-based data collection

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No