

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

PURI

<https://redirect.ema.europa.eu/resource/50456>

EU PAS number

EUPAS50455

Study ID

50456

DARWIN EU® study

No

Study countries

☐ United States

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.

Study status

Finalised

Research institutions and networks

Institutions

Dynavax Technologies

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Institution

Multiple centres: 15 centres are involved in the study

Contact details

Study institution contact

Samy Chabri

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

Study start date

Actual: 07/08/2018

Data analysis start date

Actual: 30/11/2020

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

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

Study type:

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

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

Non-interventional study design, other

Non-randomized cluster design

Study drug and medical condition

Name of medicine

HEPLISAV B

Study drug International non-proprietary name (INN) or common name

HEPATITIS B SURFACE ANTIGEN

Anatomical Therapeutic Chemical (ATC) code

(J07BC01) hepatitis B, purified antigen

hepatitis B, purified antigen

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

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)

Special population of interest

Immunocompromised

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.

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

Data sources

Data source(s), other

KPSC Research Data Warehouse

Data sources (types)

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

[Disease registry](#)

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

[Other](#)

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No