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

First published: 01/02/2024

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Institution

Multiple centres: 15 centres are involved in the study

Contact details

Study institution contact

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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:

Non-interventional study

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

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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)

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