Post-Marketing Observational Surveillance Study to Evaluate the Occurrence of Acute Myocardial Infarction in Adults 18 Years of Age and Older Who Receive HEPLISAV-B® Compared with Another Hepatitis B Vaccine (DV2-HBV-25)

First published: 03/02/2023

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS50452

Study ID

50453

DARWIN EU® study

No

Study countries

United States

Study description

The primary objective of this observational surveillance study was to compare the occurrence of confirmed acute myocardial infarction (AMI) in recipients of HEPLISAV-B and recipients of another hepatitis B vaccine. For the final study analysis, potential AMI events were abstracted from electronic health record (EHR) and redacted of hepatitis B vaccination information. The primary analyses were based on confirmed type 1 AMI events using a Cox proportional hazards model employing inverse probability of treatment weighting (IPTW) to compare rates between the two vaccine groups.

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

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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: 03/01/2018

Study start date

Actual: 07/08/2018

Data analysis start date

Actual: 30/11/2020

Date of final study report

Actual: 29/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Dynavax Technologies Corporation

Study protocol

DV2-HBV-25-mi-protocol-v0.2-9May18.pdf (305.72 KB)

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 compare the occurrence (rate) of confirmed acute myocardial infarctions between patients who received HEPLISAV-B and those who received Engerix-B.

Study Design

Non-interventional study design

Cluster design

Cohort

Other

Non-interventional study design, other

Non-randomized cluster design

Study drug and medical condition

Medicinal product name

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

Acute myocardial infarction

Population studied

Short description of the study population

The study population included patients with acute myocardial infarction, aged 18 years or older, received HEPLISAV-B vaccine, registered in KPSC research data warehouse.

Inclusion Criteria:

1. Received at least one 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 in the 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

Other

Special population of interest, other

Patients with myocardial infarction and hepatitis B virus

Estimated number of subjects

69.625

Study design details

Outcomes

The outcome of interest was the first occurrence of Acute Myocardial Infarction (AMI) during the 13-month follow-up period for each patient. Confirmed AMI was

defined as definite plus probable type 1 AMI., Unconfirmed type 1 AMI events using a historical comparator. This outcome was used for the final analysis of unconfirmed type 1 AMI events as well as the secondary analysis using a historical comparator. Type 1 AMI events in the historical comparator analysis were not adjudicated.

Data analysis plan

Baseline demographic and medical factors compared using standardized difference scores; multivariable Cox proportional hazards model applying inverse probability of treatment weighting (IPTW) for the analysis of AMI.

Data management

ENCePP Seal

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

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