Post-marketing observational surveillance study to evaluate pregnancy outcomes among women who receive Heplisav-B or Engerix-B (DV2-HBV-28)

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Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000304

EU PAS number

EUPAS1000000304

Study ID

1000000304

DARWIN EU® study

No

Study countries

United States

Study description

This observational retrospective cohort study, conducted by Kaiser Permanente Southern California (KPSC) was conducted to assess the risk of pregnancy outcomes among women who received Heplisav-B or Engerix-B during 28 days prior to conception or pregnancy.

• Pregnancy outcomes: spontaneous abortion, induced abortion, and stillbirth

• Outcomes among live births:
o Assessed at birth: preterm birth, low birth weight, and small for gestational age
o Assessed at birth through 6 months of age: major birth defects

Study status

Finalised

Research institutions and networks

Institutions

Kaiser Permanente Southern California (KPSC)

First published: 01/02/2024

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Institution

Dynavax Technologies

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Institution

Contact details

Study institution contact

Firat Pinar

Study contact

firat.pinar@propharmagroup.com

Primary lead investigator

Robert Janssen

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 07/08/2018

Study start date

Actual: 11/08/2022

Date of final study report

Actual: 09/07/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Dynavax Technologies Corporation

Study protocol

1611-prot-amend.pdf(552.1 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study Design

Non-interventional study design

Cluster design

Cohort

Other

Non-interventional study design, other

Non-randomised 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

Population studied

Age groups

Adults (18 to < 65 years)

Special population of interest

Pregnant women

Estimated number of subjects

206

Data management

Data sources

Data source(s), other

KPSC Research Data Warehouse

Data sources (types)

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